

NO. A12-609

State of Minnesota
In Court of Appeals

BARBARA LAMERE, trustee for the heirs and next-of-kin of
Sergeant Major Thomas C. Lamere, deceased,
Appellant,

v.

ST. JUDE MEDICAL INC., AND
ST. JUDE MEDICAL S.C., INC.,
Respondents/Cross-Appellants.

**PRINCIPAL RESPONSE BRIEF AND APPENDIX OF
RESPONDENTS AND CROSS-APPELLANTS**

Edward F. Fox (#003132X)
Carrie L. Hund (#277149)
BASSFORD REMELE
A Professional Association
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707
(612) 333-3000

Attorneys for Respondents/Cross-Appellants

(Counsel for Appellant appears on reverse)

OF COUNSEL:

Scott L. Nelson
Allison M. Zieve
PUBLIC CITIZEN LITIGATION
GROUP
1600 – 20th Street N.W.
Washington, D.C. 20009
Tel: (202) 588-1000
Fax: (202) 588-7795

Anthony J. Nemo (#221351)
Andrew Davick (#332719)
MESHBESHER & SPENCE, LTD.
1616 Park Avenue South
Minneapolis, MN 55404
Tel: (612) 339-9121
Fax: (612) 339-9188

James T. Capretz
Anthony Chu
CAPRETZ & ASSOCIATES
5000 Birch Street, Suite 2500
Newport Beach, CA 92660-2139
Tel: (949) 724-3000
Fax: (949) 757-2635

Attorneys for Appellant

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
LEGAL ISSUES	1
STATEMENT OF THE CASE.....	1
STATEMENT OF THE FACTS.....	3
A. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act and Premarket Approval Process.	4
B. PMA Approval of the St. Jude Medical Standard Bi-Leaflet Mechanical Heart Valve in 1982, and Manufacture of the Decedent’s Heart Valve in 1987.	6
C. Appellant’s Failure to Establish a Violation of any Federal Requirement.	7
STANDARD OF REVIEW	10
ARGUMENT	11
I. THE TRIAL COURT PROPERLY GRANTED ST. JUDE MEDICAL SUMMARY JUDGMENT BECAUSE, AFTER OVER ONE YEAR OF DISCOVERY, APPELLANT NEVER CONNECTED HER PRETENDED STATE LAW MANUFACTURING DEFECT CLAIM TO ANY VIOLATION OF ANY FEDERAL LAW REQUIREMENT.....	11
A. <i>Riegel</i> Applies to Any State Law Claim involving a PMA Approved Class III Medical Device.....	11
B. Any State Law Claim that Fails to Implicate a Violation of a Federal Requirement is Preempted.	14
C. Appellant Failed to Identify a Violation of Federal Law.....	16
D. Appellant’s First-Time Reference to CGMP’s Cannot Support Her Claim.	18
II. APPELLANT’S CAUSE OF ACTION WAS TIME-BARRED BY BOTH THE CALIFORNIA AND MINNESOTA LIMITATIONS PERIODS.....	20

A. Appellant’s Claim is Time-Barred by the California Statute of Limitations.	22
B. Appellant’s Claim is also Time-Barred Under Minnesota Law.	22
1. The trial court erred in ruling that this action is not time-barred under Minnesota’s wrongful death limitations period.	23
2. The trigger for the six-year limitation provision is the date of the defendant’s allegedly wrongful act or omission, not the date of death or some other “manifestation” of injury.	26
3. There is no “discovery rule” applicable to this wrongful death action.	28
C. The Trial Court’s Flawed Conflict of Law Analysis Caused it to Erroneously Conclude that Minnesota’s Limitations Period Applies.	30
CONCLUSION	35

TABLE OF AUTHORITIES

	Page
<u>Federal Cases</u>	
<i>Adkins v. CYTYC Corp.</i> , 2008 WL 2680474 (W.D. Va. July 3, 2008).....	14
<i>Anthony v. Stryker</i> , 2010 WL 1387790 (E.D. Ohio, Mar. 31, 2010).....	14
<i>Bausch v. Stryker Corp.</i> , 630 F.3d 546 (7th Cir. 2010).....	20
<i>Bentzley v. Medtronic, Inc.</i> , 827 F. Supp. 2d 443 (E.D. Pa. 2011)	17
<i>Clark v. Medtronic, Inc.</i> , 572 F. Supp. 2d 1090 (D. Minn. 2008)	13
<i>Covert v. Stryker Corp.</i> , 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009).....	14
<i>Delaney v. Stryker Orthopaedics</i> , 2009 WL 564243 (D.N.J. Mar. 5, 2009).....	14
<i>Fredin v. Sharp</i> , 176 F.R.D. 304 (D. Minn. 1997).....	30
<i>Funk v. Stryker</i> , 673 F. Supp. 2d 522 (S.D.Tex. 2009)	14
<i>Gross v. Stryker Corp.</i> , CIV. 11-1229, 2012 WL 876719 (W.D. Pa. Mar. 14, 2012)	19
<i>Heisner v. Genzyme Corp.</i> , 2010 WL 894054 (N.D. Ill. Mar. 8, 2010).....	14
<i>Horowitz v. Stryker Corp.</i> , 613 F. Supp. 2d 271 (E.D.N.Y 2009)	14, 19
<i>Hughes v. Wal-Mart Stores, Inc.</i> , 250 F.3d 618 (8th Cir. 2001)	34

<i>Ilarraza v. Medtronic, Inc.</i> , 677 F. Supp. 2d 582 (E.D.N.Y. 2009)	14,16, 17, 18, 19
<i>In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation</i> , 592 F. Supp. 2d. 1147 (D. Minn. 2009)	1, 18, 19
<i>In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation</i> , 623 F.3d 1200 (8th Cir. 2010).....	passim, 13, 16, 17, 19
<i>Kemp v. Medtronic, Inc.</i> , 231 F.3d 216 (6th Cir. 2000).....	6, 12, 13, 17
<i>Lemelle v. Stryker Orthopaedics</i> , 698 F. Supp. 2d 668 (W.D.La. 2010).....	14
<i>Lewkut v. Stryker Corp.</i> , 2010 WL 1544275 (S.D.Tex. Apr.16, 2010)	14
<i>Medtronic v. Lohr</i> , 518 U.S. 470 (1996).....	12
<i>Parker v. Stryker Corp.</i> , 584 F. Supp. 2d 1298 (D. Colo. 2008).....	16, 17
<i>Prudhel v. Endologix</i> , 2009 WL 2045559 (E.D. Cal. July 9, 2009)	14
<i>Riegel v. Medtronic, Inc.</i> , 552 U.S. 312 (2008).....	passim, 2, 4, 5, 6, 7, 8, 10, 11, 12, 13, 14, 15
<i>Riley v. Cordis Corp.</i> , 625 F. Supp. 2d 769 (D. Minn. 2009).....	13, 15, 16, 17
<i>Rollins v. St. Jude Medical</i> , 583 F. Supp. 2d 790 (W.D. La. 2008).....	14
<i>Steen v. Medtronic, Inc.</i> , 2010 WL 2573455 (N.D. Tex. June 25, 2010)	14
<i>The Harrisburg v. Rickards</i> , 119 U.S. 199 (1886).....	31
<i>Walker v. Medtronic, Inc.</i> , 670 F.3d 569 (4th Cir. 2012).....	6, 7, 16, 17

<i>Williams v. Cyberonics, Inc.</i> , 654 F. Supp. 2d 301 (E.D.Pa.2009)	16, 17
<i>Wolicki-Gables v. Arrow Int'l, Inc.</i> , 634 F.3d 1296 (11th Cir. 2011).....	16
<i>Yost v. Stryker Corp.</i> , 2010 WL 1141586 (M.D. Fla. March 23, 2010).....	14
<u>State Cases</u>	
<i>Amaral v. Saint Cloud Hosp.</i> , 598 N.W.2d 379 (Minn. 1999).....	25
<i>Berghis v. Korthuis</i> , 37 N.W.2d 809 (Minn. 1949).....	24
<i>Bonhiver v. Fugelso, Porter, Simich and Whiteman, Inc.</i> , 355 N.W.2d 138 (Minn. 1984).....	24, 25, 26, 29
<i>Cargill Inc. v. Jorgenson Farms</i> , 719 N.W.2d 226 (Minn. Ct. App. 2006)	10, 12
<i>Cashman v. Hedberg</i> , 10 N.W.2d 388 (Minn. 1943).....	23, 24, 29
<i>Danielson v. Nat'l Supply, Co.</i> , 670 N.W.2d 1 n. 2. (Minn. Ct. App. 2003)	21, 31
<i>DeCosse v. Armstrong Cork Co.</i> , 319 N.W.2d 45 (Minn. 1982).....	passim
<i>Erickson v. Sunset Mem'l Park Ass'n</i> , 108 N.W.2d 434 (Minn. 1961).....	25
<i>Francis v. Hansing</i> , 449 N.W.2d 479 (Minn. Ct. App. 1989).....	29
<i>Frank's Nursery Sales, Inc. v. City of Roseville</i> , 295 N.W.2d 604 (Minn. 1980).....	25
<i>Gavenda v. Ortiz</i> , 590 N.W.2d 119 (Minn. 1999).....	24, 29
<i>In re Daniel's Estate</i> , 294 N.W. 465 (Minn. 1940).....	22, 31

<i>In re Medtronic Spring Fidelis Lead Products Liability State Court Litigation</i> , 2009 WL 3417867 (Minn. Dist. Hennepin Co. Oct. 20, 2009)	13
<i>Jepson v. Gen. Cas. Co. of Wis.</i> , 513 N.W.2d 467 (Minn. 1994).....	33, 34
<i>Kensinger v. Kippen</i> , 390 N.W.2d 815 (Minn. Ct. App. 1986)	26
<i>Milkovich v. Saari</i> , 203 N.W.2d 408 (1973)	32
<i>Mitaro v. Medtronic, Inc.</i> , 2009 WL 1272398 (N.Y. Sup. April 9, 2009)	14
<i>Murphy v. Allina Health System</i> , 668 N.W.2d 17 (Minn. Ct. App. 2003)	26, 29
<i>Negaubauer v. Great Northern Ry. Co.</i> , 99 N.W. 620 (Minn. 1904).....	31
<i>Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.</i> , 590 N.W.2d 670 (Minn. Ct. App.1999)	34
<i>Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.</i> , 604 N.W.2d 91 (Minn. 2000).....	32, 33, 34
<i>Owens v. Federated Mut. Implement & Hardware Ins.</i> , 328 N.W.2d 162 (Minn. 1983).....	25
<i>Patton v. Yarrington</i> , 472 N.W.2d 157 (Minn. Ct. App. 1991).....	26
<i>Reed v. Univ. of N.D.</i> , 543 N.W.2d 106 (Minn. Ct. App. 1996).....	33
<i>Riverview Muir Doran, LLC v. JADT Dev. Grp., LLC</i> , 790 N.W.2d 167 (Minn. 2010).....	10
<i>Rugland v. Anderson</i> , 15 N.W. 676 (Minn. 1883).....	24
<i>Thiele v. Stich</i> , 425 N.W.2d 580 (Minn. 1988).....	18

<i>Van Asperen v. Darling Olds, Inc.</i> , 93 N.W.2d 690 (Minn. 1958).....	25
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<i>Wolfer v. Microboards Mfg., LLC</i> , 654 N.W.2d 360 (Minn. Ct. App. 2002)	27
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Federal Statutes

21 U.S.C. § 360c(a)(1)(C)(ii).....	4
21 U.S.C. § 360c, et seq.....	4
21 U.S.C. § 360e(c)(1)	13
21 U.S.C. § 360e(d)(6).....	5
21 U.S.C. § 360k(a).....	2, 6, 10, 14, 15, 18

State Statutes

Minn. Stat. § 541.051	26
Minn. Stat. § 541.30, et seq.....	30
Minn. Stat. § 541.31, subd. 1 (2004).....	31, 32
Minn. Stat. § 573.02, subd. 1 (2002).....	1, 2, 4, 22, 23, 25, 30

State Rules

Minn. R. Civ. P. 56.03	10
------------------------------	----

Federal Regulations

21 C.F.R. § 814.39(c).....	5
21 C.F.R. § 820.1(a)(1)	18
21 C.F.R. §§ 820.70, 820.72, and 820.90	19

LEGAL ISSUES

1. Whether the trial court erred as a matter of law in granting St. Jude Medical summary judgment ruling that Appellant's state law claims were preempted when, after one year of discovery, Appellant failed to identify any federal specification or requirement that St. Jude Medical allegedly violated in manufacturing the Decedent's heart valve in 1987, as required to establish a non-preempted claim.

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200 (8th Cir. 2010).

In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d. 1147 (D. Minn. 2009).

2. Whether the trial court erred as a matter of law in denying St. Jude Medical summary judgment and finding that Appellant's claims were not time-barred by the expiration of the limitations periods prescribed by the pertinent states' wrongful death statutes because the action was not commenced within two years of the Decedent's death or within six years of the wrongful act or omission that allegedly caused his death.

Cal. Code Div. Proc. §§ 377.60-377.62, 335.1.

Minn. Stat. § 573.02.

DeCosse v. Armstrong Cork Co., 319 N.W.2d 45 (Minn. 1982).

STATEMENT OF THE CASE

Appellant is the Trustee for the heirs and next-of-kin of her husband, both long-time California residents. Appellant commenced this wrongful death lawsuit in Minnesota against the St. Jude Medical Respondents on July 9, 2010, alleging that the bi-

leaflet mechanical heart valve manufactured by St. Jude Medical in 1987, and implanted in the Decedent in 1988, contained a manufacturing defect that allegedly caused his death nearly twenty years later in September 2007. Appellant's claims, purportedly brought under Minnesota's wrongful death statute, Minn. Stat. § 573.02, sounded in strict liability, negligence, breach of warranty and fraud theories.

In October 2010, St. Jude Medical moved for summary judgment on two grounds. First, that the Appellant's claims were preempted by federal law under the Medical Device Amendments of 1976 ("MDA") to the federal Food, Drug and Cosmetic Act ("FDCA"), 28 U.S.C. § 360(k)(a) as applied in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and its progeny. Second, Appellant's claims were also time-barred by both the California two-year statute of limitations as well as the limitations periods prescribed in Minnesota's wrongful death statute, Minn. Stat. § 573.02, which requires that any wrongful death action "must be commenced within six years of the [wrongful] act or omission" that caused the death. By order of February 7, 2011, the district court granted the motion, in part, dismissing all of Appellant's claims as preempted by federal law but allowing her to amend her complaint to attempt to state a non-preempted manufacturing defect claim. The district court found the action was not time-barred.

Following the close of over one year of discovery, on December 21, 2011, St. Jude Medical renewed its summary judgment motion on the grounds that Appellant had not stated or established a manufacturing defect claim that was not preempted by federal law. The district court granted the Summary Judgment Motion and dismissed Appellant's sole remaining manufacturing defect claim on the grounds that she had failed to establish the

essential element of showing that St. Jude Medical violated any federal requirement in the manufacture of the heart valve and, therefore, she had not established a viable non-preempted claim. In fact, Appellant argued that she did not need to satisfy this irrefutable element of a viable, non-preempted parallel claim.

The district court entered judgment on the February 7, 2011 and January 18, 2012 Orders on March 21, 2012.

STATEMENT OF THE FACTS

At all pertinent times, both the Decedent and his wife, Appellant Barbara Lamere, resided in California. AA-1.¹ Appellant's wrongful death action arises from St. Jude Medical's manufacture and sale of a standard bi-leaflet mechanical heart valve, Model 33M-101. The valve was manufactured in October of 1987, and implanted into Thomas Lamere (USMC Retired) ("Decedent") on February 4, 1988. AA-3. Following the Decedent's death nearly twenty years later on September 20, 2007, Appellant commenced this Minnesota lawsuit on July 9, 2010, with vague and non-specific allegations that St. Jude Medical "defectively manufactured," "inspected and sold" the Decedent's heart valve. RA 1-11. The action, brought more than two years and nine months after the Decedent's death, and more than twenty years after St. Jude Medical manufactured and sold the Decedent's allegedly defective heart valve, is preempted by federal law and is also time-barred under any applicable limitations period. *Riegel v.*

¹ References to Appellant's Appendix are cited as "AA-__". References to Respondents'/Cross-Appellants' Appendix are cited as "RA __."

Medtronic, Inc., 552 U.S. 312 (2008); Cal. Code Div. Proc. §§ 377.60-377.62, 335.1; Minn. Stat. § 573.02.

A. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act and Premarket Approval Process.

In 1976, Congress stepped into the inconsistent and unworkable patchwork of State-based regulation of medical devices with the passage of the Medical Device Amendments of 1976 (“MDA”) to the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 360c, *et seq.* The MDA swept back these inconsistent state regulations and imposed a specific regime of federal oversight for review and approval of medical devices by the Food and Drug Administration (“FDA”).

Under this regulatory scheme, the FDA assigns medical devices to one of three Classes (Class I, II and III), each with increasing levels of federal oversight, depending on the risks they present. *Riegel*, 552 U.S. at 317. Class III medical devices receive the most federal oversight. *Id.* A medical device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is “purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,” or “presents a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(a)(1)(C)(ii).

The MDA also established a “rigorous regime” of premarket approval (“PMA”) for new Class III devices. *Riegel*, 552 U.S. at 317. That rigorous PMA process requires the manufacturer of a new Class III medical device to submit a multi-volume application

to the FDA that includes, among many other things, a “full statement” of the device’s “components, ingredients, and properties and of the principle or principles of operation”; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device”; and samples or device components as required by the FDA. *Id.* at 318 (citation omitted) (emphasis added). The FDA spends an average of 1200 hours reviewing each PMA application, and weighs any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. *Id.* (citation omitted). The FDA “may approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives.” *Id.*

Once a device has received PMA approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. 21 U.S.C. § 360e(d)(6)(A)(i). If the manufacturer wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, which is evaluated under largely the same criteria as an initial application. 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c).

The MDA includes an express preemption provision that states:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.” 21 U.S.C. § 360k(a).

Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). The federal device-specific requirements are defined by the PMA application and approval. *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012).

B. PMA Approval of the St. Jude Medical Standard Bi-Leaflet Mechanical Heart Valve in 1982, and Manufacture of the Decedent’s Heart Valve in 1987.

The St. Jude Medical standard bi-leaflet mechanical heart valve that is the subject of Appellant’s action is a Class III medical device that received PMA approval from the FDA on December 17, 1982. RA 18. In the nearly thirty years since it received PMA approval, St. Jude Medical has manufactured and sold over 2,000,000 heart valves. RA 16. The FDA has never taken any formal regulatory action premised on any allegation that the bi-leaflet mechanical heart valve does not comply with the federal requirements imposed by the FDA through the PMA process. RA 19.

The mechanical heart valve that is the subject of this lawsuit was manufactured by St. Jude Medical in October of 1987 and implanted into the Decedent on February 4, 1988. RA 19. The Decedent’s heart valve, which Appellant alleges had a “manufacturing defect” or “production error,” performed flawlessly for nearly twenty years. RA 20. The Decedent’s heart valve was designed, manufactured, and inspected in accordance with all applicable PMA requirements, as documented through the manufacturing and quality control record known as the “Traveler.” RA 19-20. St. Jude Medical maintains these quality control records “in the ordinary course of business to record the manufacturing

and inspection history of each individual product manufactured to ensure that product's compliance with all FDA-approved specifications and processes." RA 15-16. The Traveler for the Decedent's mechanical heart valve establishes that the valve was manufactured in accordance with all FDA requirements. RA 19-20.

Appellant's Complaint vaguely alleged that St. Jude Medical "defectively manufactured," prepared, "inspected and sold" the Decedent's heart valve. RA 1-11. To resist St. Jude Medical's initial summary judgment motion, Appellant relied upon the October 26, 2010 Affidavit of Constantine Armeniades ("Armeniades Affidavit"), which vaguely described an alleged defect in one of the valve's component pyrolytic carbon leaflets. A. Add. 28a-30a.² Critically, Dr. Armeniades never, in his Affidavit or at any time during the litigation below, identified any federal requirement that St. Jude Medical allegedly violated in manufacturing the Decedent's heart valve. *Id.*

C. Appellant's Failure to Establish a Violation of any Federal Requirement.

The Supreme Court's *Riegel* decision made it clear that essentially all state law tort claims attacking a PMA-approved Class III medical device manufactured in compliance with its PMA requirements, like the Decedent's mechanical heart valve, are expressly preempted. 552 U.S. at 330. Accordingly, on February 7, 2011, the trial court granted St. Jude Medical summary judgment dismissing all of Appellant's claims as preempted by federal law. A. Add. 20a-27a. Nevertheless, the district court allowed Appellant to amend her Complaint to attempt to articulate a viable, "parallel"

² References to Appellant's Addendum are cited as "A. Add. ___."

manufacturing defect claim. A “parallel” claim, which would not be expressly preempted by federal law, is a state law cause of action that implicates a violation of a specific federal requirement. *Riegel*, 552 U.S. at 330; A. Add. 27a. Appellant attempted to state such a claim by cutting and pasting sections of the deficient Armeniades Affidavit into her Amended Complaint, but still failed to identify a violation of any federal requirement. AA-4 – AA-7.

From August 2010 through the close of discovery on November 18, 2011, St. Jude Medical produced over nine thousand pages of documents in response to Appellant’s discovery requests. These documents included, but were not limited to: (1) the Investigational Device Exemption (“IDE”) Application #G800061 and Supplements; (2) the complete PMA Application Number P810002 and Supplements for the St. Jude Medical bi-leaflet heart valve that received the FDA’s PMA approval on December 17, 1982; (3) communications and submissions with the FDA related to the St. Jude Medical bi-leaflet heart valve, PMA No. P810002; (4) St. Jude’s internal manufacturing specifications, inspection criteria, and engineering specifications for the component pyrolytic carbon leaflets; (5) the manufacturing and inspection data records for the lot of pyrolytic carbon leaflets used in the Decedent’s heart valve; and (6) the manufacturing Traveler and corresponding manufacturing, inspection, testing and quality assurance reports for the Decedent’s bi-leaflet heart valve model 33M-101, serial number 166155, documenting its manufacturing and inspection history. RA 25-26.

Despite having all of this comprehensive technical data as well as the artifacts of the Decedent’s valve, Appellant never identified any federal manufacturing requirement

allegedly violated in connection with the manufacture of Decedent's valve, in general, or its pyrolytic carbon components, in particular. Simply put, none of Appellant's original, supplemental, nor amended supplemental discovery responses, nor her required expert witness disclosures, ever articulated this indispensable element of a viable parallel claim.

A. Add. 28a-30a; RA 29-49.

Appellant's October 4, 2011 Supplemental Answers to Interrogatories and Responses to Request for Production of Documents identified Dr. Armeniades as her only expert witness and defaulted to his original, deficient Affidavit to state the "facts and opinions" supporting her claim. RA 29-32. Neither the Armeniades Affidavit nor Appellant's final supplemental discovery responses identified any federal requirement with which the subject bi-leaflet valve allegedly failed to comply. A. Add. 28a-30a; RA 29-32.

Appellant's October 21, 2011 Supplemental Answers to Interrogatories also identified Dr. Armeniades as her sole expert witness to provide evidence of a "manufacturing defect" but, again, Appellant referred only to the same, insufficient, Armeniades Affidavit. RA 33-38. Finally, on November 18, 2011, the very last day of the discovery period, Appellant served Amended Supplemental Answers to Interrogatories and Responses to Request for Production of Documents. RA 39-49. Though she attempted to assert further detail to describe the alleged "manufacturing defect" in the subject valve, Appellant again failed to identify any specific federal requirement with which the subject valve failed to comply, nor did she amend her responses to St. Jude Medical's expert discovery requests. *Id.*

In fact, given the complete absence of any evidence of such a violation, Appellant instead resorted to making the astonishing declaration that she “[d]oes not believe that a violation of a FDA approved manufacturing specification or requirement is necessary to establish a manufacturing defect....” RA 41-42, 43, 45. Appellant is, of course, incorrect. *Riegel* and its progeny leave no doubt that the only type of state-law claim that escapes express preemption under § 360k(a) is a “parallel” claim, *i.e.*, a state law claim that involves violation of a specific federal requirement. A. Add. 5a.

STANDARD OF REVIEW

An appellate court reviews a district court's summary judgment decision de novo. *Riverview Muir Doran, LLC v. JADT Dev. Grp., LLC*, 790 N.W.2d 167, 170 (Minn. 2010). A motion for summary judgment shall be granted when the “pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that either party is entitled to a judgment as a matter of law.” Minn. R. Civ. P. 56.03. Summary judgment is also appropriate “when the record is devoid of proof on an essential element of the plaintiff's claim.” *Cargill Inc. v. Jorgenson Farms*, 719 N.W.2d 226, 232 (Minn. Ct. App. 2006).

ARGUMENT

I. THE TRIAL COURT PROPERLY GRANTED ST. JUDE MEDICAL SUMMARY JUDGMENT BECAUSE, AFTER OVER ONE YEAR OF DISCOVERY, APPELLANT NEVER CONNECTED HER PRETENDED STATE LAW MANUFACTURING DEFECT CLAIM TO ANY VIOLATION OF ANY FEDERAL LAW REQUIREMENT.

Appellant's "manufacturing defect" claim was an allegation that was never established. The trial court had to dismiss this case on summary judgment because Appellant never cited a single federal requirement that St. Jude Medical purportedly violated in connection with the manufacture and release of the subject heart valve upon which to base a non-preempted claim.

A. *Riegel* Applies to Any State Law Claim involving a PMA Approved Class III Medical Device.

Appellant's discussion of the law is so incomplete and inaccurate that St. Jude Medical must reluctantly suggest that Appellant misrepresents the applicable law with respect to PMA-approved medical devices and turns black-letter preemption law from across the country on its head. As explained below, the United States Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and its progeny, provide the

applicable preemption law because, like the device in *Riegel*, the bi-leaflet mechanical heart valve is a Class III medical device that received the FDA's PMA approval in 1982.³

Appellant's attempt to differentiate between design/labeling defect claims versus manufacturing defect claims is also a false distinction. The argument that *Riegel* does not apply to state common law manufacturing defect claims is without merit and directly contrary to every case on point establishing the preemptive effect of the MDA on manufacturing defect claims. In *Riegel*, the Supreme Court made it clear that Congress's reference in the MDA preemption provision to a State's "requirements" most certainly "includes its common law duties." *Id.* at 324. Contrary to Appellant's assertion, the Supreme Court drew no distinction between state law design or labeling duties and state law manufacturing duties but, instead, referred generally to negligence and strict liability claims, such as the strict liability claim presented here. *Id.* at 232-24. Indeed, the Court stated, "in the context of [MDA] legislation, excluding common-law duties from the scope of pre-emption would make little sense." *Id.* at 324-25. *Kemp*, 231 F.3d at 220 (jury verdict finding manufacturer negligent for failing to manufacture [approved medical

³ Appellant's reliance on *Medtronic v. Lohr*, 518 U.S. 470 (1996) is completely misplaced because the holding in *Lohr* is confined to medical devices cleared through the much less rigorous 510(k) "substantial equivalence" process, not the PMA process. See *Riegel*, 552 U.S. at 322-23 (contrasting *Lohr*'s 510(k) process with PMA process, and reaching opposite result regarding preemption for PMA devices).

It is very misleading for Appellant to suggest that the device here falls under the *Lohr* holding because that case dealt with a device reviewed and approved under a completely different regulatory statute and process. The *Riegel* decision, issued ten years later, is directly on point and could not be clearer that claims brought with respect to Class III medical devices with PMA approval, like the mechanical heart valve at issue here, are preempted.

device] with a process or specification different than what the FDA approved would be to impose a requirement “different from and in addition to” those established by the FDA).

Courts in Minnesota and across the country have applied the MDA and *Riegel* to dismiss all types of claims based on state law duties, including manufacturing defect claims such as that presented by Appellant here.⁴ See *In re Medtronic, Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1205 (8th Cir. 2010) (the MDA preempts “all manner of claims from strict product liability and negligence, to breach of warranty, to failure to warn, manufacturing- and design-defect, to negligence per se.”); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (same); *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090 (D. Minn. 2008); *In re Medtronic Spring Fidelis Lead Products Liability State Court Litigation*, 2009 WL 3417867 (Minn. Dist. Hennepin

⁴ Appellant’s suggestion that manufacturing defect claims escape preemption is frivolous. As the Supreme Court noted in *Riegel*, a PMA application, which defines the federal requirements that apply to an innovative Class III device (*see, e.g., Kemp*, 231 F.3d at 228), must contain “a full description of the methods used in, and the facilities and controls used for, the manufacture . . . of, such device.” *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(c)(1)).

Co. Oct. 20, 2009), unpublished (negligence, failure to warn, design defect, manufacturing defect, and express and implied warranty claims preempted).⁵

B. Any State Law Claim that Fails to Implicate a Violation of a Federal Requirement is Preempted.

Contrary to Appellant’s argument, *Riegel* plainly holds that any state law claim relating to the safety or effectiveness of a PMA-approved device, including a manufacturing defect claim, that fails to implicate a violation of the FDCA is preempted by the MDA. 552 U.S. at 330. The Supreme Court in *Riegel* recognized that the MDA expressly preempts state requirements “different from, or in addition to, any requirement applicable ... to the device” under federal law. *Id.* at 321. The Court then held that (1) premarket approval imposes “requirements” under the MDA that are specific to individual devices, *Id.* at 322-23 (“[premarket approval] is federal safety review”) (emphasis in original)), and (2) state law causes of action for negligence and strict

⁵ *Lewkut v. Stryker Corp.*, 2010 WL 1544275, at *7 (S.D.Tex. Apr.16, 2010) (applying Section 360(k) broadly, preempting all manner of claims from strict products liability and negligence ... to failure to warn and manufacturing-and-design defect); *Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668 (W.D.La. 2010) (same); *Funk v. Stryker*, 673 F. Supp. 2d 522, 531 (S.D.Tex. 2009) (same); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *2-*7 (D.N.J. Mar. 5, 2009) (same); *Horowitz v. Stryker*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (same); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582 (E.D.N.Y. 2009) (same); *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D. La. 2008) (same); *Steen v. Medtronic, Inc.*, 2010 WL 2573455 (N.D. Tex. June 25, 2010) (same); *Anthony v. Stryker*, 2010 WL 1387790 (E.D. Ohio, Mar. 31, 2010) (same); *Yost v. Stryker Corp.*, 2010 WL 1141586 (M.D. Fla. March 23, 2010) (same); *Heisner v. Genzyme Corp.*, 2010 WL 894054 (N.D. Ill. Mar. 8, 2010) (same); *Covert v. Stryker Corp.*, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009); *Prudhel v. Endologix*, 2009 WL 2045559 (E.D. Cal. July 9, 2009) (same); *Mitaro v. Medtronic, Inc.*, 2009 WL 1272398 (N.Y. Sup. April 9, 2009) (same); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (D. Colo. 2008) (same); *Adkins v. CYTYC Corp.*, 2008 WL 2680474 (W.D. Va. July 3, 2008) (same).

liability impose “requirements,” that are preempted by federal requirements specific to a medical device. *Id.* at 323-24.

Therefore, under the MDA and *Riegel*, all state law claims, including manufacturing defect claims, that relate to the safety and effectiveness of a PMA-approved medical device are preempted except those that implicate a violation of the FDCA such that the state law duties “parallel,” rather than add to, federal requirements. *Riegel*, 552 U.S. at 330; *Riley*, 625 F. Supp. 2d at 777 (emphasis added).⁶ Thus, state law tort claims relating to the safety or effectiveness of an innovative Class III device that complied with the terms of its PMA approval are preempted because such claims necessarily would impose requirements that are “in addition to” or “different from” the FDA’s PMA approval and would thereby impinge on the FDA’s exclusive regulatory authority over the approval of Class III medical devices. General statements of state law tort claims, like Appellant’s “manufacturing defect” claim here, do not satisfy this standard.

⁶ Moreover, a violation of federal law alone cannot create a state law claim. Rather, a plaintiff must identify the violation of an independent state law duty that also happens to violate the “parallel” requirements of federal law. The Eighth Circuit articulated this point in *In re Medtronic, Inc.*, as follows:

Riegel and *Buckman* create a narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777).

C. Appellant Failed to Identify a Violation of Federal Law.

In an attempt to skirt her evidentiary obligations, Appellant resorted to contending that “Plaintiff does not believe that a violation of a FDA approved manufacturing specification or requirement is necessary to establish a manufacturing defect...”. RA 41-42, 43, 45. This assertion is a bold misstatement of the law which directly contradicts the fundamental, essential elements of a viable parallel claim under the MDA, *Riegel*, and its progeny.

To avoid summary judgment, Appellant was required to identify and produce evidence which implicates a violation of a specific FDCA requirement imposed through the PMA process. *In re Medtronic*, 623 F.3d at 1206; *Riley*, 625 F. Supp. 2d at 789 (dismissing manufacturing defect claim); *Walker*, 670 F.3d at 578 (affirming summary judgment for manufacturer where plaintiff failed to establish manufacturer's noncompliance with any federal requirement); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1302 (11th Cir. 2011)(affirming summary judgment dismissing manufacturing defect claim where plaintiff failed to identify any federal specification allegedly violated); *Ilarraza*, 677 F. Supp. 2d at 589 (same); see *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 307 (E.D.Pa.2009) (granting summary judgment on manufacturing defect claims where plaintiff failed to show that device departed from any specific FDA-approved standards); *Parker*, 584 F. Supp. 2d at 1301 (plaintiff's state law claim must implicate a violation of specific PMA requirements) (emphasis added).

This Court will search the record in vain for Appellant's reference or citation to any federal requirement that St. Jude Medical allegedly violated in connection with the

manufacture of the mechanical heart valve. Instead of producing evidence of this essential element of her claim, Appellant simply asserted that she did not have to allege or establish this essential element of her manufacturing defect claim. RA 41-42, 43, 45. Her position is both contrary to black-letter law and fatal to her cause of action.

Appellant's failure to identify any such federal requirement means she cannot satisfy an essential element of her "parallel" state law claim. Appellant had every opportunity to prove the viability of her claim. The federal requirements applicable to the valve are set forth in the device's PMA application, supplemental PMA applications, and the FDA's letters of approval. *See Kemp*, 231 F.3d at 228; *see also Walker*, 670 F.3d at 579 n.5. St. Jude Medical produced all of these documents to Appellant. Yet, despite having access to the relevant federal requirements, Appellant failed to identify any federal requirement from which St. Jude Medical allegedly departed in connection with the manufacture of the Decedent's heart valve. Her failure to do so required dismissal of her claim on summary judgment, which this Court should affirm. *See In re Medtronic*, 623 F.3d at 1206; *Riley*, 625 F. Supp. 2d at 789; *Walker*, 670 F.3d at 578; *Wolicki-Gables*, 634 F.3d at 1302; *Ilarraza*, 677 F. Supp. 2d at 589; *Williams*, 654 F. Supp. 2d at 307; *Parker*, 584 F. Supp. 2d at 130; *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 455-56 (E.D. Pa. 2011) (granting manufacturer summary judgment when plaintiff has failed to produce any evidence that his device departed from FDA manufacturing standards and therefore was defective).

D. Appellant's First-Time Reference to CGMP's Cannot Support Her Claim.

Tacitly conceding that her state claim must also implicate a violation of a federal requirement if it is to survive express preemption under § 360k(a), Appellant—referring to the FDA's Current Good Manufacturing Practices (CGMPs)—argues for the first time on appeal that her manufacturing defect claim survives preemption because it, purportedly, “runs parallel to the requirements imposed by the GMP regulations.” Br. 23.⁷ There is no basis for this argument with respect to CGMPs because Appellant never identified in the litigation below any CGMP that St. Jude Medical allegedly violated. The Court will see that her arguments lack any pertinent citation to the record, and they cannot be raised for the first time on appeal. *See Thiele v. Stich*, 425 N.W.2d 580, 582 (Minn. 1988); RA 44-46. Thus, Appellant forfeited this argument by failing to raise it or supporting facts below.

Even if it had not been forfeited, the argument is without merit. First, the great weight of authority from Minnesota and around the country holds that a violation of a CGMP cannot support a parallel claim. The FDA acknowledges that the CGMPs “are intended to serve only as ‘an umbrella quality system,’ providing ‘general objectives’ medical-device manufacturers must seek to achieve.” *In re Medtronic*, 592 F. Supp. 2d at 1157 (citation omitted); *see also Ilarraza*, 677 F. Supp. 2d at 588 (CGMPs are “intentionally vague and open-ended”). *Ilarraza*, 677 F. Supp. 2d at 588 (CGMPs do not

⁷ The FDA and the industry use the terms Quality System Regulations (“QSRs”), which were established by the FDA and also set forth Current Good Manufacturing Practices (“CGMPs”). 21 C.F.R. § 820.1(a)(1).

address the specific aspects of a particular medical device’s design, production, and marketing requirements.) (emphasis added). Because the CGMPs “do not provide such a fine level of detail concerning the manufacture [of a medical device],” each device manufacturer has the discretion to establish its own manufacturing procedures (to the extent those procedures are not set forth in the PMA application). *In re Medtronic*, 592 F. Supp. 2d at 1158; *accord Horowitz*, 613 F. Supp. 2d at 279 (concluding, “The CGMP requirements, therefore, leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective”). Therefore, most state and federal courts have held that CGMPs are too general to form the basis for a parallel claim. *See, e.g., In re Medtronic*, 592 F. Supp. 2d at 1157 (plaintiff’s claims were “simply too generic, standing alone” to serve as basis for manufacturing-defect claim), *aff’d*, 623 F.3d 1200 (8th Cir. 2010); *Horowitz*, 613 F. Supp. 2d at 284 (same); *Ilarraza*, 677 F. Supp. 2d at 588 (same); *Gross v. Stryker Corp.*, CIV. 11-1229, 2012 WL 876719 at *23 (W.D. Pa. Mar. 14, 2012) (same). Accordingly, because the highly general CGMPs do not create device-specific federal requirements, any state law tort claim involving a purported violation of a CGMP would necessarily impose a state law requirement that is “different from, or in addition to” the federal requirements applicable to that device.

Second, Appellant has failed to identify—much less offer any evidence of— any CGMP that St. Jude Medical allegedly violated in manufacturing the Decedent’s heart valve. While mentioning 21 C.F.R. §§ 820.70, 820.72, and 820.90, Appellant nowhere claims, let alone offers any evidence, that St. Jude Medical ever violated those

provisions.⁸ Of course, the PMA requirements, manufacturing specifications, and quality assurance procedures produced in discovery along with the Traveler irrefutably established that the heart valve complied with and satisfied all of the applicable “production and control processes” at the time it left St. Jude Medical’s control over twenty-five years ago. RA 19-20.

Therefore, the trial court appropriately granted St. Jude Medical summary judgment after finding that Appellant failed to offer any proof sufficient to create an issue of fact on her “parallel claim” that St. Jude Medical did not manufacture the valve in compliance with the FDA’s PMA approval. This Court should affirm the trial court’s ruling.

II. APPELLANT’S CAUSE OF ACTION WAS TIME-BARRED BY BOTH THE CALIFORNIA AND MINNESOTA LIMITATIONS PERIODS.

Appellant’s claim should be dismissed because it is also time-barred by the limitations periods of both California and Minnesota. The trial court’s flawed analysis of Minnesota’s wrongful death limitations periods led to its erroneous conclusion that the claim is not-time barred under Minnesota law. From that conclusion, the trial court then incorrectly ruled, based on a faulty conflict of laws analysis, that the (apparent) outcome-determinative conflict between California’s and Minnesota’s laws is “procedural,” and

⁸ The few cases Appellant cites in support of her contention that she can rely on CGMPs to support her manufacturing defect claim are readily distinguishable because the courts in those cases found that the plaintiffs had identified a specific CGMP that the device manufacturers allegedly violated and most involved early Rule 12 motions. *See, e.g., Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010). This case was in an entirely different posture on summary judgment because, after over a year of discovery, Appellant never even identified, let alone presented evidence of, a violation of any CGMP or any other federal specification or requirement.

(incorrectly) automatically applied Minnesota's law to Appellant's California-centered claim.

First, in concluding that Appellant's cause of action is not time-barred by Minnesota's wrongful death statute, the trial court incorrectly interpreted and construed the statute in ruling that "this wrongful death action 'accrues either upon the manifestation of the fatal disease[,] ... or upon the date of death – whichever is earlier.'" A. Add. 16a (quoting *DeCosse v. Armstrong Cork Co.* 319 N.W.2d 45, 52 (Minn. 1982)). The trial court also misapplied and expanded the limited *DeCosse* holding, which was confined to and "dictated by the unique character of an asbestos-related disease." 319 N.W.2d at 48-49. Therefore, because this action is time-barred under both California and Minnesota law, there is no outcome determinative conflict and the trial court should have dismissed the case on this basis.

Nevertheless, after the trial court incorrectly ruled that the action is not time barred under Minnesota law, it also conducted a flawed conflict of law analysis. The trial court mistakenly relied upon Minnesota cases addressing common law statutes of limitations in support of its conclusion that the limitations provisions in the Minnesota wrongful death statute are "procedural" and, therefore, Minnesota automatically applies the law of the forum state. A. Add. 17a-19a. Contrary to the trial court's ruling, the limitations periods expressed within statutes that create a cause of action, like the Minnesota wrongful death statute, are "substantive." *Danielson v. Nat'l Supply, Co.*, 670 N.W.2d 1, 6 n. 2. (Minn. Ct. App. 2003) (The limitations period is substantive because "the limitation period [acts

as] a condition of the right rather than as an actual statute of limitations.”); *In re Daniel’s Estate*, 294 N.W. 465, 470 (Minn. 1940).

When, as here, the “apparent” conflict in two states’ laws involves a substantive law, the trial court should have conducted a choice-of-law analysis using Minnesota’s choice-of-law rules. Accordingly, under a proper choice-of-law analysis, the substantive law of the state with the strongest governmental interest – California – should apply to this case.

A. Appellant’s Claim is Time-Barred by the California Statute of Limitations.

Appellant conceded that her cause of action, which she filed two years and nine months after her husband died, was barred by California’s two-year statute of limitations⁹ by failing to address that argument in opposing St. Jude Medical’s October 28, 2010, summary judgment motion on that ground, and the trial court appropriately so found. A. Add. 10a. Accordingly, Appellant’s claim is plainly time-barred.

B. Appellant’s Claim is also Time-Barred Under Minnesota Law.

Minnesota’s wrongful death statute, which conditions Appellant’s right to bring a wrongful death cause of action, provides that:

When death is caused by the wrongful act or omission of any person or corporation....Any other action under this section may be commenced within three years after the date of death provided that the action must be commenced within six years after the act or omission.

Minn. Stat. § 573.02, subd. 1 (2002) (emphasis added).

⁹ Cal. Code Div. Proc. §§ 377.60-377.62, 335.1.

1. **The trial court erred in ruling that this action is not time-barred under Minnesota's wrongful death limitations period.**

In *Cashman v. Hedberg*, 10 N.W.2d 388, 391 (Minn. 1943), the Minnesota Supreme Court observed that a cause of action for wrongful death was not recognized at common law and that compliance with the conditions imposed by the statute creating the cause of action relate to the right to bring suit in the first instance, not the remedy. In *Cashman*, the court stated:

It is established, however, by the weight of authority, and followed by this state, that, since a wrongful death statute creates a right of action which did not exist at common law and is a condition affecting the right rather than the remedy, ordinarily neither express nor implied provisions which toll general limitation statutes will extend the limitation period in a wrongful death statute in the absence of a saving clause in the latter statute.

Id. (emphasis added).

The Court ruled that it would make no exception to the limitations period provided by a statute granting a statutorily created right unless that statute contains a clause stating that general tolling statutes or other exceptions apply. *Id.* It then went on to examine legislative intent through such indicia as the time of enactment, statutory language, and legislative history as that history interwove with previous decisions, and concluded that failure to strictly comply with the wrongful death limitations period bars commencement of an action for wrongful death. *Id.* 393-94.

Both before and after *Cashman*, Minnesota courts have consistently confirmed the necessity of filing a wrongful death action in strict compliance with the time limitations fixed by Minnesota's wrongful death statutes [§ 573.02]. In *Ortiz v. Gavenda*, the

Minnesota Supreme Court observed, “[o]ver one hundred years ago we held that because the wrongful death statute itself made no exceptions to the time limit for bringing a wrongful death action, no exceptions could be made by construction.” 590 N.W.2d 119, 122 (Minn. 1999) (emphasis added) (citing *Rugland v. Anderson*, 15 N.W. 676 (Minn. 1883)); *Berghis v. Korthuis*, 37 N.W.2d 809, 810 (Minn. 1949) (“This period fixing the time within which the right of action for wrongful death may be exercised is not an ordinary statute of limitations. It is considered a condition precedent to the right to maintain the action, and the lapse of such period is an absolute bar. It conditions the right.”) (emphasis added); *Cashman*, 10 N.W.2d at 390; *Bonhiver v. Fugelso, Porter, Simich and Whiteman, Inc.*, 355 N.W.2d 138, 141 (Minn. 1984). “Because the right to maintain an action for wrongful death is created by statute and is in derogation of the common law, the requirements of the statute have been strictly construed.” *Bonhiver*, 355 N.W.2d at 141.

The limitations provisions in statutorily created causes of action, like the wrongful death statute, are jurisdictional, requiring dismissal for failure to strictly comply with the statutory conditions. *See Gavenda*, 590 N.W.2d at 122. As creatures of statute, wrongful death actions do not have flexible parameters permitting the statutory conditions to be ignored if their application is too technical. *Id.*

Minnesota’s wrongful death statute plainly imposes two separate limitations periods, both of which must be satisfied as a condition precedent to bringing a wrongful death action: (1) the action may be commenced within three years after the date of death; and (2) the action must be commenced within six years after the allegedly wrongful act or

omission that allegedly caused the death. Minn. Stat. § 573.02, subd. 1 (emphasis added). By their plain language, they refer and apply to two different but interrelated triggering events: the former refers to the date of death, and the latter refers to the act or omission that allegedly caused the death. No other reading is possible under the plain language of the statute.¹⁰

The Minnesota Supreme Court confirmed this interpretation with its pronouncement first enunciated in *DeCosse* and reiterated in *Bonhiver*:

The current version, enacted in 1978 [citation]¹¹, also presents the possibility that a wrongful death action could expire *before death* by limiting the bringing of actions to six years after the *act or omission*.

¹⁰ When interpreting a statute, the court must first look to see whether the statute's language, on its face, is clear or ambiguous. *See Amaral v. Saint Cloud Hosp.*, 598 N.W.2d 379, 384 (Minn. 1999). “A statute is only ambiguous when the language therein is subject to more than one reasonable interpretation.” *Id.* Basic canons of statutory construction instruct that courts are to construe words and phrases according to their plain and ordinary meaning. *See Frank's Nursery Sales, Inc. v. City of Roseville*, 295 N.W.2d 604, 608 (Minn. 1980). A statute should be interpreted, whenever possible, to give effect to all of its provisions; “no word, phrase, or sentence should be deemed superfluous, void, or insignificant.” *Amaral*, 598 N.W.2d at 384 (citing *Owens v. Federated Mut. Implement & Hardware Ins.*, 328 N.W.2d 162, 164 (Minn. 1983)). Courts are to read and construe a statute as a whole and must interpret each section in light of the surrounding sections to avoid conflicting interpretations. *See Van Asperen v. Darling Olds, Inc.*, 93 N.W.2d 690, 698 (Minn. 1958); *see also Erickson v. Sunset Mem'l Park Ass'n*, 108 N.W.2d 434, 441 (Minn. 1961). Finally, courts should construe a statute to avoid absurd results and unjust consequences. *See Erickson*, 108 N.W.2d at 441. When construing a statute, the goal is to ascertain and effectuate the intention of the legislature. *See Amaral*, 598 N.W.2d at 385–86.

¹¹ The *DeCosse* and *Bonhiver* courts were discussing the 1978 amendment to § 573.02, subdivision 1, which is identical to the current § 573.02, subdivision 1. *See DeCosse*, 319 N.W.2d at 48; *Bonhiver*, 355 N.W.2d at 142.

DeCosse, 319 N.W.2d at 48; *Bonhiver*, 355 N.W.2d at 142 (emphasis added). The Minnesota Supreme Court acknowledged that the mandatory six-year limitations period can be triggered – and expire – before death or any accident or event that may result in death, and said as much, “[B]y the 1978 amendment the legislature is expressing its intention to bar actions for some deaths caused by wrongful acts or omissions even if they are brought on the day of death.” *Id.* (emphasis added);¹² see also *Murphy v. Allina Health System*, 668 N.W.2d 17, 22 (Minn. Ct. App. 2003) (“Consequently, some wrongful-death actions may be barred under the statute even if they are brought on the day of death.”), review denied (Minn. Nov. 18, 2003); *Kensinger v. Kippen*, 390 N.W.2d 815, 817 (Minn. Ct. App. 1986) (same).

2. The trigger for the six-year limitation provision is the date of the defendant’s allegedly wrongful act or omission, not the date of death or some other “manifestation” of injury.

Despite the wrongful death statute’s plain language and the Minnesota Appellate Courts’ pronouncements on the effect of that language and its strict construction, the trial court ruled that Appellant’s cause of action was not time-barred finding that “[t]his wrongful death action ‘accrues either upon the manifestation of the fatal disease in a way that is causally linked to [the product], or upon death – whichever is earlier,’” and “the applicable triggering event is Lamere’s death.” A. Add. 16a, 17a.

¹² The same basic principle has been applied for analogous statutes. For instance, in a products liability case involving a similar statute of repose relating to deaths arising from defects in improvements to real property (Minn. Stat. § 541.051), the Minnesota Court of Appeals held that the limitations period began running on the date of the manufacture of the allegedly defective smoke detector that caused a fire seven years after manufacture, as opposed to the date of the fire causing the deaths. *Patton v. Yarrington*, 472 N.W.2d 157, 161 (Minn. Ct. App. 1991).

In *DeCosse*, the Minnesota Supreme Court clearly recognized that a wrongful death action can, in fact, be foreclosed even before death. This precedent plainly established that the correct interpretation of the statute means that the date triggering the start of the limitation period is the date St. Jude Medical manufactured the allegedly defective heart valve. With its ruling, the trial court impermissibly expanded the limitations period to twenty-three years after its supposedly wrongful act or omission that allegedly caused the Decedent's death.

Equating the statutory phrase "act or omission" with the date of the "manifestation" or occurrence resulting in death, as the trial court did in ruling that this cause of action was not time-barred, is neither a permissible nor a reasonable construction of the statute, but instead is inconsistent with the plain statutory language for several reasons. First, as the introductory language makes clear, the antecedent to the "act or omission" phrase refers to the "wrongful act or omission" of the defendant, and the statute itself draws a clear distinction between the "date of death" and the defendant's "wrongful act or omission." There is no basis to interpret the phrase "act or omission" as equating to the date of death (with its own separate, shorter limitations provision). Doing so strains and distorts the statutory language and would, in effect, always result in a three-year limitations period after the date of death regardless of the date of the "wrongful act or omission," which is clearly contrary to the express statutory language and legislative intent. If this Court accepts the trial court's interpretation, the six-year limitations period triggered by date of the "wrongful act or omission" would be rendered a nullity. *Wolfer v. Microboards Mfg., LLC*, 654 N.W.2d 360, 365 (Minn. Ct. App.

2002) (rejecting statutory interpretation that renders a provision a nullity, which would violate basic tenet of statutory construction).

The legislature clearly intended to link the six-year provision of the statute to the defendant's alleged "wrongful act or omission" and not the date of death or any other "manifestation," "accident," or "occurrence" ultimately causing the death. All of these latter terms have clear legal meanings and implications, but the legislature did not select them and, instead, intended to cut off stale claims like this one by specifically linking the six-year provision of the statute to the time of the defendant's "act or omission." In essence, the plain statutory language creates a six-year repose period after which one loses the right to bring a wrongful death action under the statute – even if the death does not occur until years, or even decades later.

Here, St. Jude Medical's last involvement with the device was almost 20 years before the date of death. Many more than six years had long since expired after any potential "wrongful act or omission." In fact, nearly twenty-three years passed between the alleged wrongful act or omission and Appellant's commencement of her action. These circumstances demonstrate just the sort of wrongful death action that the legislature plainly intended to bar. *DeCosse; Bonhiver; Murphy; and Kensinger*.

3. There is no "discovery rule" applicable to this wrongful death action.

In ruling that this cause of action "accrues either upon the manifestation of the fatal disease in a way that is causally linked to [the product], or upon death," the trial court also improvidently, and without sound legal basis, effectively expanded the

wrongful death statute to include a discovery rule where none exists in or is permitted under the statute's plain language. In fact, the Minnesota Supreme Court has expressly rejected a "discovery rule" for the accrual of wrongful death claims under this statute. See *Murphy*, 668 N.W.2d at 22; accord, *Francis v. Hansing*, 449 N.W.2d 479, 482 (Minn. Ct. App. 1989). The *DeCosse* court carved out a narrow exception to this rule by holding that asbestos-related wrongful death claims were subject to a discovery rule while emphasizing that this exception was strictly limited to asbestos claims because of their "unique character." 319 N.W.2d at 48, 52. Subsequent cases recognize the *DeCosse* exception as applicable solely to asbestos-related claims. See, e.g., *Bonhiver*, 355 N.W.2d at 142. No Minnesota case has used *DeCosse* to apply a discovery rule in a non-asbestos wrongful death case.

In order to salvage Appellant's untimely action, the trial court's ruling, in effect, expands the strictly limited *DeCosse* exception to apply to all products liability cases where there is no "manifestation" of an alleged product defect or product-related injury or disease for years or decades so as to conflate the date of the alleged wrongful act or omission with the date of death. The lower court's expansion of the Minnesota Supreme Court's narrow ruling in *DeCosse* was neither permitted nor warranted under a plain reading of the statute or case law. *Gavenda*, 590 N.W.2d at 122 (the wrongful death statute itself makes no exceptions to the time limit for bringing a wrongful death action and none can be made by construction.); *Cashman*, 10 N.W.2d at 391 (tolling does not apply to wrongful death actions). Because no "discovery rule" applies in this products liability wrongful death action, the trial court erred in ruling that Appellant's action is not

time-barred under Minn. Stat. § 573.02, subd. 1. This Court should reverse that ruling and dismiss the action as time-barred.

Thus, there is no outcome-determinative conflict because Appellant's cause of action is barred by both California and Minnesota law. If this Court decides that the trial court's construction of Minnesota's wrongful death statute was correct, thus creating a conflict between California and Minnesota law, California law and its limitations period should still apply to this California-based claim.

C. The Trial Court's Flawed Conflict of Law Analysis Caused it to Erroneously Conclude that Minnesota's Limitations Period Applies.

The only reason there is an apparent conflict of law is because the trial court misconstrued Minnesota's limitation period. Even if the trial court were correct in its interpretation of Minnesota's wrongful death limitations provisions and Appellant's right to bring an action under that statute is not barred, the cause of action is time-barred nonetheless under a proper choice-of-law analysis and the Uniform Conflicts of Law – Limitations Act, Minn. Stat. § 541.30, *et seq.*

First, the trial court's "conflicts of law" determination that the applicable limitations period question is "procedural" such that the law of the forum state [Minnesota] applies, was erroneous. An exception to the general rule—that statutes of limitations are procedural—exists where a statute of limitations does not merely bar the remedy for the violation of a right, but limits or conditions the right itself. *Fredin v. Sharp*, 176 F.R.D. 304, 308-09 (D. Minn. 1997). Thus, under Minnesota law, a

limitations period is “substantive” when it applies to a right created by statute, as opposed to a right recognized at common law. As the Minnesota Supreme Court has explained:

Where the time limitation conditions the right, it fixes the time within which suit must be brought wherever the right may be asserted. The time so fixed is regarded as a condition and not a statute of limitation. The *lex loci* [i.e. California] therefore governs as to the time within which such actions must be brought.

In re Daniel's Estate, 294 N.W. 465, 470 (Minn. 1940)(citing *Negaubauer v. Great Northern Ry. Co.*, 99 N.W. 620 (Minn. 1904); *Danielson*, 670 N.W.2d at 6 n. 2; accord, *The Harrisburg v. Rickards*, 119 U.S. 199, 214 (1886) (where the statute includes a limitations provision, “[t]he time within which the suit must be brought operates as a limitation of the liability itself as created, and not of the remedy alone[;][i]t is a condition attached to the right to sue at all”) (citations omitted)).

Contrary to the trial court’s ruling, Minnesota’s limitations provisions do not automatically apply here (as forum law) because the limitations provisions in Minnesota’s wrongful death statute are substantive.¹³ Rather, when faced with the perceived conflict between California’s and Minnesota’s limitations periods, the trial court should have either (1) applied California’s limitation period to this California-centered claim under Minn. Stat. §541.31, subd. 1(a)(1), or (2) conducted a choice-of-law analysis to determine which state’s limitations period applies – California’s or

¹³ In support of its finding that the limitations periods are “procedural,” the trial court improperly relied upon Minnesota cases analyzing common law statutes of limitations, which are generally procedural, rather than cases addressing limitations periods contained within statutorily created causes of action, like Minnesota’s wrongful death statute, which are substantive.

Minnesota's. *Milkovich v. Saari*, 203 N.W.2d 408 (1973) (adopting Professor Lefflar's five choice-influencing factors analysis in deciding substantive conflicts); *see also* Minn. Stat. §541.31, subd. 1(a)(2) (2004)¹⁴.

Appellant and Decedent were long-time California residents, Decedent's physicians replaced his diseased mitral valve with the subject mechanical heart valve in California on February 4, 1988, the Decedent lived and received all of his medical care, including his valve replacement surgery and subsequent care and treatment, in California, and the Decedent lived and worked with the mechanical heart valve in California for nearly twenty years until September 20, 2007. RA 1-13; AA- 1-10. Given that the clear center of gravity of this case is grounded in California, California's substantive products liability law applies to this case. Accordingly, under Minn. Stat. § 541.31, subd. 1(a)(1), the Minnesota court would, in essence, "borrow" California's two-year statute of limitations and apply it to this cause of action.

Likewise, if the court were to find that both California and Minnesota substantive law could conceivably apply, a choice-of-law analysis called for under either *Milkovich* or Minn. Stat. § 541.31, subd. 1(a)(2), which are one and the same, also dictates application of California's law over Minnesota's in this California-grounded action. Under a choice-of law analysis, the court must evaluate five factors to determine which state's law applies. *Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 604 N.W.2d 91, 94 (Minn. 2000). Those factors include: "(1) predictability of the result; (2) maintenance of

¹⁴ "If a claim is substantively based: (1) upon the law of one other state, the limitation period of that state applies; or (2) upon the law of more than one state, the limitation period of one of those states chosen by the conflict of laws of this state applies."

interstate order; (3) simplification of the judicial task; (4) advancement of the forum's governmental interests; and (5) application of the better rule of law.” *Jepson v. Gen. Cas. Co. of Wis.*, 513 N.W.2d 467, 470 (Minn. 1994). Minnesota courts have indicated that the first and third factors have little value in tort cases, *see id.* at 470–72, and the fifth factor does not carry much weight in a choice-of-law analysis. *Id.* at 473 (“Sometimes different laws are neither better nor worse in an objective way, just different.”); *see also Nodak*, 604 N.W.2d at 96 (“[T]his court has not placed any emphasis on this [better rule of law] factor in nearly 20 years.”).

In considering the second factor, maintenance of interstate order, the court is to assess whether the application of Minnesota law would “manifest disrespect” for California’s sovereignty. *Jepson*, 513 N.W.2d at 471. Evidence of forum shopping or evidence that application of one state’s law would promote forum shopping, would be an attempt to evade, and would indicate disrespect for, California law. *Id.* Minnesota does not encourage forum shopping “because it frustrates the maintenance of interstate order.” *See Reed v. Univ. of N.D.*, 543 N.W.2d 106, 109 (Minn. Ct. App. 1996). The application of Minnesota law in this case would promote forum shopping. By passing establishing limiting the time for commencing wrongful death actions in California to two years, California has stated its public policy interest in encouraging the early commencement of such actions to avoid stale claims. Applying Minnesota’s law in the face of such a public policy would indicate disrespect for California law.

The Eighth Circuit has held that where a state “has little or no contact with a case and nearly all of the significant contacts are with a sister state, the factor suggests that a

state should not apply its own law to the dispute.” *Hughes v. Wal-Mart Stores, Inc.*, 250 F.3d 618, 620–21 (8th Cir. 2001). In *Hughes*, the Eighth Circuit determined that Louisiana law should apply in a products liability action where the defendant's principal place of business was in Arkansas, but where the product at issue was purchased in Louisiana, the injury occurred in Louisiana, and the plaintiff was a Louisiana resident. Like *Hughes*, California has the overwhelming number of contacts with the case regardless of where the heart valve was manufactured, and the second factor therefore weighs in favor of applying California law.

Under the fourth factor, the court considers “which choice of law most advances a significant interest of the forum.” *Jepson*, 513 N.W.2d at 471. “When one of two states related to a case has a legitimate interest in the application of its law and policy and the other has none, ... clearly the law of the interested state should be applied.” *Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 590 N.W.2d 670, 674 (Minn. Ct. App.1999) (internal quotation marks omitted). In these circumstances, California clearly has a strong interest in having the rights of its citizens adjudicated with its own law when injuries occur within its borders. Conversely, Minnesota would have very little, if any, interest in adjudicating those rights on these facts. Thus, the fourth factor also weighs in favor of applying California law.

The balance of relevant factors clearly favors the application of California’s law. Further, even if the choice-of-law analysis did not favor either state’s law, the state where the injury occurred has the strongest governmental interest; and accordingly, the law of the state where the injury occurred should be applied. *Nodak*, 604 N.W.2d at 96. Here,

the injury occurred exclusively in California. For over forty years, the Decedent lived and worked in California, received his heart valve in California, received all of his subsequent medical care and treatment in California, and died in California. Thus, under Minnesota Supreme Court precedent, in these circumstances California's governmental interest dictates that California's limitation period apply to this substantive law question.

Appellant's cause of action is time-barred under California and Minnesota law. In the unlikely event the trial court correctly ruled that Minnesota law does not bar this action, this Court should still apply California law because California is the state with the most significant contacts and governmental interest in the claim.

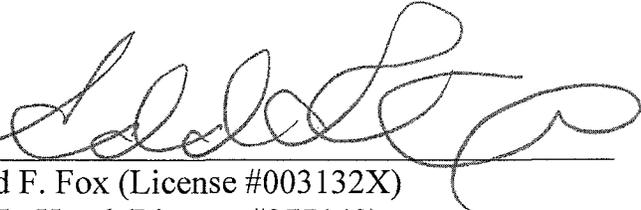
CONCLUSION

Based upon the foregoing arguments and authorities, the St. Jude Medical Respondents respectfully request that the Court: (1) affirm the trial court's dismissal of Appellant's cause of action on the grounds of federal preemption because she failed to identify any violation of any federal requirement upon which to base a non-preempted, parallel state law claim; and (2) reverse the trial court's statute of limitations ruling and direct that Appellant's cause of action is time-barred by the California and Minnesota limitations periods.

Respectfully submitted,

BASSFORD REMELE
A Professional Association

Dated: 7/23/12

By 

Edward F. Fox (License #003132X)

Carrie L. Hund (License #277149)

33 South Sixth Street, Suite 3800

Minneapolis, Minnesota 55402-3707

Telephone: (612) 333-3000

Facsimile: (612) 333-8829

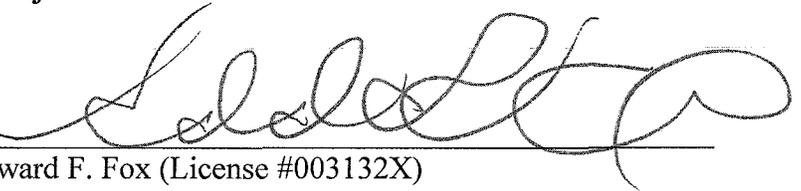
*ATTORNEYS FOR ST. JUDE MEDICAL, INC. and
ST. JUDE MEDICAL, S.C., INC.*

CERTIFICATE OF WORD COUNT COMPLIANCE

The undersigned, counsel for the St. Jude Medical Respondents/Cross-Appellants, in compliance with Minnesota Rules of Civil Appellate Procedure certifies as follows:

- (1) That the Principal Response Brief of Respondents/Cross-Appellants was prepared in 13-point, proportionately-spaced typeface, using Microsoft Word 2010; and
- (2) That the Brief contains 9614 words, based upon a word processing count that was designed to include all text, including headings, footnotes, and quotations.

BASSFORD REMELE
A Professional Association

By 

Edward F. Fox (License #003132X)
Carrie L. Hund (License #277149)
33 South Sixth Street, Suite 3800
Minneapolis, Minnesota 55402-3707
Telephone: (612) 333-3000
Facsimile: (612) 333-8829

*ATTORNEYS FOR RESPONDENTS AND CROSS-
APPELLANTS*