

**STATE OF MINNESOTA  
IN COURT OF APPEALS  
A12-0609**

Barbara A. Lamere,  
Trustee for the heirs and next-of-kin of  
Sergeant Major Thomas C. Lamere, deceased,  
Appellant,

vs.

St. Jude Medical, Inc., et al.,  
Respondents.

**Filed February 19, 2013  
Affirmed in part and reversed in part;  
motion denied  
Stauber, Judge**

Ramsey County District Court  
File No. 62-CV-10-7618

Anthony J. Nemo, Andrew L. Davick, Rachel Simpson, Ashleigh Raso, Meshbeshier and Spence, Ltd., Minneapolis, Minnesota; and

Scott L. Nelson, Public Citizen Litigation Group, Washington, D.C. (for appellant)

Edward F. Fox, Carrie L. Hund, Bassford & Remele, P.A., Minneapolis, Minnesota (for respondents)

Considered and decided by Stauber, Presiding Judge; Schellhas, Judge; and Collins, Judge.\*

**S Y L L A B U S**

1. Pursuant to Minn. Stat. § 573.02 (2012), the statute of limitations on a wrongful-death claim arising out of an alleged product defect begins to run at the time the alleged

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\* Retired judge of the district court, serving by appointment pursuant to Minn. Const. art. VI, § 10.

wrongdoing occurred, not at the time the decedent discovered or could have discovered his injury.

2. To successfully plead a parallel claim to avoid federal preemption, a plaintiff must do more than merely cite to a federal Good Management Practice (GMP) that may have been violated.

3. State common-law strict-liability claims impose general requirements that are different from federal device-specific requirements and therefore are preempted by 21 U.S.C. § 360k(a) (2006).

## **OPINION**

**STAUBER**, Judge

On appeal from summary judgment, appellant argues that the district court erred by concluding that appellant's manufacturing-defect claim was preempted by the Medical Device Amendments (MDA) of 1976 to the federal Food, Drug and Cosmetic Act. By notice of related appeal, respondent argues that the district court erred by concluding that appellant's claim is not time-barred under Minnesota's wrongful-death statute of limitations. Because we conclude that a claim arises at the time the alleged wrong-doing occurred, we reverse the district court's order and hold that appellant's manufacturing-defect claim is time-barred, and affirm the district court's award of summary judgment. And because we conclude that the appeal is meritorious, we deny respondent's motion for sanctions pursuant to Minn. Stat. § 549.211 (2012).

## FACTS

In February 1988, Thomas C. Lamere (Mr. Lamere), a California resident, underwent a successful surgical implantation of a mechanical heart valve to replace his mitral heart valve. The heart valve implanted in Mr. Lamere was a St. Jude Medical Mechanical Heart Valve, Model No. 33M-101, Serial Number 166155. In September 2007, Mr. Lamere died. An autopsy was performed, and the medical examiner concluded that Mr. Lamere's death was likely a result of "acute heart failure, secondary to a displacement of one of the mechanical heart valve leaflets."

Appellant Barbara A. Lamere (Ms. Lamere), Mr. Lamere's wife and also a California resident, brought suit in Ramsey County District Court on July 9, 2010, against respondents St. Jude Medical, Inc., et al. (St. Jude). Ms. Lamere's complaint asserted numerous claims, including wrongful death, loss of consortium, strict liability (manufacturing defect), breach of express and implied warranty, negligence, misrepresentation, and fraud. St. Jude moved for summary judgment, arguing that Ms. Lamere's claims were barred by the applicable statutes of limitation, under either Minnesota or California law, and preempted by the Medical Device Amendments (MDA) of 1976 to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k.

In opposition to the motion for summary judgment, Ms. Lamere provided the affidavit of Dr. Richard I. Fukumoto, M.D., who performed the autopsy on Mr. Lamere and concluded that the cause of death was likely related to the failure of the mechanical heart valve. Ms. Lamere also provided the affidavit of Dr. Constantine D. Armeniades, a professor emeritus at Rice University in the department of Chemical and Biomolecular

Engineering. Dr. Armeniades stated that he examined Mr. Lamere's mechanical heart valve using an electron microscope and observed "pores near the fracture and crevasses on the fracture surface" indicating that "[t]hese defects led to the formation and propagation of cracks, which eventually caused the valve leaflet to fracture and separate." In Dr. Armeniades's opinion, "the fracture of . . . [Mr.] Lamere's valve was caused by a manufacturing defect which occurred due to the failure to properly finish and polish the valve leaflet, and failure to detect its flaws during the post-manufacture inspection."

In support of its motion for summary judgment, St. Jude presented the affidavit of Michael F. Coyle, its regulatory-affairs manager. Included as an attachment to the affidavit was the "Traveler," a document that recorded each federally required step in the device's manufacturing process. According to Coyle, the Traveler "reflects that the Model 33M-101 Standard Bi-leaflet Mechanical Heart Valve, serial number 166155 completed all manufacturing processes, inspections, and quality control processes satisfactorily with no discrepancies noted, meaning that . . . [it] complied with all FDA requirements at the time it was shipped out of St. Jude's custody and control."

The district court issued its order on February 7, 2011, denying St. Jude's motion for summary judgment on statute-of-limitations grounds. The district court concluded that Minnesota's wrongful-death statute does not bar Ms. Lamere's claim because the event that caused the limitations period to run was Mr. Lamere's injury and death, not the implantation or manufacture of the device as claimed by St. Jude. In its choice-of-law analysis, the district court concluded that Minnesota's three-year statute of limitations

applied and not California's two-year statute of limitations because statutes of limitation are procedural, not substantive, and the procedural law of the forum state applies.

However, the district court granted St. Jude's motion for summary judgment on preemption grounds on all of Ms. Lamere's claims except her claim that the device was damaged in the manufacturing process. The district court concluded that the affidavit of Dr. Armeniades created a genuine issue of material fact as to whether the mechanical valve was manufactured in accordance with the applicable federal rules and that such a claim is not preempted by federal law because it parallels the federal requirements and does not add a new or different requirement.

Following several months of discovery, St. Jude again moved for summary judgment, arguing that Ms. Lamere failed to present any evidence that St. Jude violated any federal rules with respect to its manufacture of the device implanted in Mr. Lamere, and therefore her claim was preempted because Ms. Lamere failed to present evidence of a parallel claim. The district court granted St. Jude's motion for summary judgment, concluding that Ms. Lamere failed to cite any federal requirement that St. Jude failed to follow, and that Ms. Lamere's common-law claim based in either negligence or strict liability is preempted by federal law.

This appeal followed. Ms. Lamere contested the district court's grant of summary judgment on federal-preemption grounds. St. Jude also appealed, contesting the district court's denial of summary judgment on the statute-of-limitations issue, and moved for sanctions pursuant to Minn. Stat. § 549.211.

## ISSUES

I. Did the district court err by denying summary judgment on the statute-of-limitations issue, concluding that Ms. Lamere's wrongful-death claim is not time-barred by Minn. Stat. § 573.02?

II. Did the district court err by granting summary judgment in favor of St. Jude, concluding that Ms. Lamere's manufacturing-defect claim is preempted by federal law?

III. Is St. Jude entitled to attorney fees under Minn. Stat. § 549.211?

## ANALYSIS

A motion for summary judgment shall be granted if “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 judgment as a matter of law.” Minn. R. Civ. P. 56.03. On an appeal from summary judgment, an appellate court “review[s] the record to determine whether there is any genuine issue of material fact and whether the district court erred in its application of the law.” *Dahlin v. Kroening*, 796 N.W.2d 503, 504-05 (Minn. 2011). Both questions are reviewed de novo. *Riverview Muir Doran, LLC v. JADT Dev. Grp., LLC*, 790 N.W.2d 167, 170 (Minn. 2010). The evidence is reviewed in the light most favorable to the party against whom judgment was granted. *Fabio v. Bellomo*, 504 N.W.2d 758, 761 (Minn. 1993). No genuine issue of material fact exists “when the nonmoving party presents evidence which merely creates a metaphysical doubt as to a factual issue and which is not sufficiently probative with respect to an essential element of the nonmoving party's case

to permit reasonable persons to draw different conclusions.” *DLH, Inc. v. Russ*, 566 N.W.2d 60, 71 (Minn. 1997).

## I.

St. Jude argues that, under either Minnesota or California law, Ms. Lamere’s manufacturing-defect claim is time-barred because her claim arose when the mechanical heart valve was manufactured prior to 1988. In the alternative, St. Jude argues that the district court should have applied California’s shorter limitations period in this case, because the case lacks sufficient ties to Minnesota for Minnesota law to be applied.

Minnesota’s statute of limitations provides that an action for wrongful death “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. Appellate courts review the interpretation and construction of a statute of limitations or repose de novo. *State Farm Fire & Cas. v. Aquila Inc.*, 718 N.W.2d 879, 883 (Minn. 2006). “If the meaning of a statute is unambiguous, [appellate courts] interpret the statute’s text according to its plain language. If a statute is ambiguous, [appellate courts] apply other canons of construction to discern the legislature’s intent.” *Brua v. Minn. Joint Underwriting Ass’n*, 778 N.W.2d 294, 300 (Minn. 2010) (citation omitted).

St. Jude argues that pursuant to the plain language of the statute Ms. Lamere’s claim is time-barred because it was not commenced within six years from the date of the “act or omission,” which it interprets as the date the mechanical heart valve was manufactured or implanted into Mr. Lamere. We agree. The Minnesota statute of

limitations clearly contemplates that some wrongful-death claims will expire prior to death:

The current version [of Minn. Stat. § 573.02] . . . 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. Time-barring a wrongful death action before death triggers accrual of the right to bring the action has been criticized as illogical and unjust. Despite any injustice or illogic to such an approach, the plain meaning of the statute seems to be clear . . . . [T]he 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.

*DeCosse v. Armstrong Cork Co.*, 319 N.W.2d 45, 48 (Minn. 1982); *cf. Murphy v. Allina Health Sys.*, 668 N.W.2d 17, 22 (Minn. App. 2003) (concluding that, with regard to a wrongful-death claim based in medical malpractice, “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).

Because we conclude that the statute is unambiguous, we must apply the statute pursuant to its plain language. *State by Beaulieu v. RSJ, Inc.*, 552 N.W.2d 695, 701 (Minn. 1996). Under the plain language of the statute, a plaintiff’s claim must be brought within six years of a defendant’s act or omission, which in this case refers either to the date the medical device was manufactured or the date it was implanted in the decedent. Moreover, this interpretation is consistent with our caselaw and with the legislative intent. *See DeRogatis v. Mayo Clinic*, 390 N.W.2d 773, 775-76 (Minn. 1986) (considering prior cases holding that a wrongful-death action may be time-barred prior to death and concluding that the wrongful-death statute of limitations for actions based in

medical malpractice does not begin to run on the date of death); *cf. Kensinger v. Kippen*, 390 N.W.2d 815, 818 (Minn. App. 1986) (referring to the wrongful-death statute of limitations for actions arising from medical malpractice and concluding that the legislature must have intended some claims to expire prior to death or it would have worded the statute differently), *review denied* (Minn. Sept. 22, 1986).

Ms. Lamere urges this court to adopt a statutory interpretation that would give effect to the legislature's intent to bar some causes of action six years from the act or omission causing death while not barring cases involving a latent injury that was not discoverable by the decedent until his death. Pointing to the exception for deaths caused by asbestos exposure, Ms. Lamere asks this court to broaden that exception to include all deaths resulting from an injury that was undiscovered by the decedent. In *DeCosse*, the Minnesota Supreme Court held that "because of the unique character of asbestos-related deaths, wrongful death actions brought in connection with those deaths accrue either upon the manifestation of the fatal disease in a way that is causally linked to asbestos, or upon the date of death—whichever is earlier." 319 N.W.2d at 52. This narrowly defined exception has not been extended beyond the facts of asbestos-related cases, and we will not extend it now. *See Francis v. Hansing*, 449 N.W.2d 479, 482 (Minn. App. 1989) (refusing to extend the *DeCosse* tolling rule and holding that the statute of limitations was not tolled by patient's failure to discover an intra-uterine device that she believed had been removed), *review denied* (Minn. Feb. 21, 1990); *see also Tereault v. Palmer*, 413 N.W.2d. 283, 286 (Minn. App. 1987) ("[T]he task of extending existing law falls to the

supreme court or to the legislature, but it does not fall to this court.”), *review denied* (Minn. Dec. 18, 1987).

Moreover, Minnesota courts have expressly rejected the “discovery rule,” thereby refusing to hold that the limitations period for wrongful death does not begin to run until the time that the decedent realized his injury. *DeCosse*, 319 N.W.2d at 52; *Broek v. Park Nicollet Health Servs.*, 660 N.W.2d 439, 444 (Minn. App. 2003), *review denied* (Minn. July 15, 2003). Ms. Lamere relies on *Broek* in support of her argument that an exception should be made for latent injuries. In that case, this court held that, “[u]nder the narrow facts of this case, because no evidence establishes that [the decedent] suffered compensable injury attributable to [the defendant’s] alleged negligence before [the decedent suffered cardiac arrest and died], we conclude that [the plaintiff’s] claim was timely brought within the applicable statutes of limitation.” *Broek*, 660 N.W.2d at 444. But we conclude *Broek* is distinguishable from the facts of this case because *Broek* involved the interpretation of the termination-of-treatment rule under Minn. Stat. §§ 573.02, subd. 1; 541.076(b) (2002), the wrongful-death statute of limitations for deaths resulting from medical malpractice. Because *Broek* was decided on the narrow facts before the court, we decline to extend the *Broek* rule to the facts of this case involving the separate issue of the interpretation of the wrongful-death statute of limitations in a product-liability case under Minn. Stat. § 573.02, subd. 1.<sup>1</sup>

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<sup>1</sup> Ms. Lamere also relies on a federal district court case, *Henry v. Raynor Mfg. Co.*, 753 F. Supp. 278, 280 (D. Minn. 1990), which held that “the phrase ‘act or omission’ refers to the date of the accident which causes death.” But “federal court interpretations of state law are not binding on state courts.” *State ex rel. Hatch v. Employers Ins. Of Wausau*,

Minnesota law recognizes only one general equitable tolling exception, which arises when the plaintiff can demonstrate that the defendant engaged in fraudulent concealment. *DeCosse*, 319 N.W.2d at 51-52. The burden is on the plaintiff to establish the elements of fraudulent concealment. *Id.* Ms. Lamere has not demonstrated that St. Jude either actively concealed a defect in its product or falsely denied knowledge of any defect. Therefore, we hold that the statute of limitations began to run in or prior to 1988 when the mechanical heart valve was either manufactured or implanted in the decedent. It thus follows that Minnesota's six-year statute of limitations has run on Ms. Lamere's claim. Because we conclude that Ms. Lamere's claim is time-barred under both Minnesota and California law, we need not reach St. Jude's alternative argument that we should apply California's statute of limitations to bar her claim.

## II.

Even if Ms. Lamere's claims were not time-barred, the district court did not err by granting St. Jude's motion for summary judgment and concluding that the claims are barred by federal preemption.

Congress enacted the Medical Device Amendments (MDA) of 1976 to "provide for the safety and effectiveness of medical devices intended for human use." *Medtronic v. Lohr*, 518 U.S. 470, 474, 116 S. Ct. 2240, 2245 (1996) (quotation omitted). "The Act classifies medical devices in three categories based on the risk that they pose to the

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644 N.W.2d 820, 828 (Minn. App. 2002). Ms. Lamere further relies on *Bonhiver v. Fugelso*, 335 N.W.2d 138, 141 (Minn. 1984), which stated in dicta that a wrongful-death suit must be brought within the statutory period following the date of the injury, not the date of defendant's tortious act. But dicta are not binding on later cases. *State v. Naftalin*, 246 Minn. 181, 208, 74 N.W.2d 249, 266 (1956).

public.” *Id.* at 476. Devices that pose the least risk are designated as Class I, devices that pose a “more harmful” risk are designated Class II, and devices that “presen[t] a potential unreasonable risk of illness or injury” are designated Class III. *Id.* at 476-77, 116 S. Ct. at 2246 (quoting 21 U.S.C. § 360c(a)(1)(C)). St. Jude’s mechanical heart valve is a Class III device.

Before a Class III device may be introduced into the market, it must undergo “premarket approval” (PMA).<sup>2</sup> *Id.* at 477, 116 S. Ct. at 2246-47. The PMA process is “rigorous.” *Id.* In the case of St. Jude’s mechanical heart valve, the PMA application took nearly two years to complete and contained “ten volumes of clinical data, design specifications, manufacturing processes, and proposed labeling.” The mechanical heart valve received federal premarket approval on December 17, 1982.

With respect to federally approved medical devices, Congress provided an express preemption provision:

[N]o 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

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<sup>2</sup> Some Class III devices may enter the marketplace without undergoing PMA if they are “substantially equivalent” to a device already on the market. 21 U.S.C. § 360(o)(1) (2006); *Lohr*, 518 U.S. at 477-78, 116 S. Ct. at 2246-47. This is called the “510(k)” process, referring to the way the statute was formerly numbered. *Lohr*, 518 U.S. at 478, 116 S. Ct. at 2247. *Lohr* involved a device that was approved through the 510(k) process, meaning it never underwent the rigorous PMA process. *Id.* In that case, a plurality of the Supreme Court concluded that the plaintiff’s state-law claims were not preempted in large part because “[t]he 510(k) process is focused on *equivalence*, not safety.” *Id.* at 493, 116 S. Ct. at 2254.

(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). In determining the proper scope of preemption, courts look to the congressional purpose of the preemption statute and begin from the assumption that congress did not intend to preempt state law “unless that was the clear and manifest purpose of Congress.” *Lohr*, 518 U.S. at 485-86, 116 S. Ct. at 2250 (quotation omitted). PMA and state common-law actions for damages both impose “requirements” within the meaning of § 360k(a). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-25, 128 S. Ct. 999, 1006-09 (2008). But state common-law duties are not preempted when they “parallel” federal requirements such that they are “equal to, or substantially identical to, requirements imposed by or under the act.” *Lohr*, 518 U.S. at 496-97, 116 S. Ct. at 2256 (quoting 21 CFR § 808.1(d)(2) (1995)). In other words, states may “provid[e] a damages remedy for claims premised on a violation of FDA regulations.” *Riegel*, 552 U.S. at 330, 128 S. Ct. at 1011.

Ms. Lamere argues that St. Jude violated federal Good Manufacturing Practices (GMPs) (also known as Current Good Manufacturing Practices (CGMPs)), and therefore her claim parallels federal requirements for the manufacture of the device at issue. The federal circuit courts are split as to whether federal GMPs may form the basis of a parallel claim. *See Bass v. Stryker Corp.*, 669 F.3d 501, 511-12 (5th Cir. 2012) (“[T]he circuits are not in complete agreement as to what constitutes a sufficient pleading with regard to a CGMP . . . .”). The Fifth, Sixth, and Seventh Circuit Courts of Appeals have all held that a plaintiff may establish a parallel claim by pleading a violation of a GMP.

*See id.*; *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010); *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436, 441 (6th Cir. 2010) (unpublished). However, the Eighth Circuit Court of Appeals has held that a violation of a GMP cannot form the basis of a parallel claim because the GMPs are simply too generic. *In re Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (“Plaintiffs’ general allegations of failure to comply with CGMPs—practices that FDA has described as ‘an umbrella quality system’ providing ‘general objectives’ for all device manufacturers—do not save these claims from preemption under § 360k because Plaintiffs failed to identify any specific requirement in the PMA approval for the [device] that forms the basis for an unpreempted parallel claim.”). GMPs impose duties on manufacturers to “develop *their own* quality-system controls,” and therefore are not device-specific requirements imposed by the federal government. *In re Medtronic, Inc.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009), *aff’d*, 623 F.3d 1200 (8th Cir. 2010). “Without any such specific requirement, Plaintiffs necessarily seek to impose requirements that differ from the [GMPs].” *Id.* at 1158.

Ms. Lamere has identified two GMPs that she believes support her parallel claim.

The first provides:

Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

21 C.F.R. § 820.70(a). The other GMP identified by Ms. Lamere provides in pertinent part:

Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance.

21 C.F.R. § 820.90(a). Ms. Lamere argues that these provisions were violated when St. Jude manufactured a mechanical heart valve that contained “pores and crevasses creating an unacceptable risk that the device would develop cracks and ultimately break.”

Without concluding that a GMP may never form the basis of a valid parallel claim, we hold that in this case Ms. Lamere failed to sufficiently plead a parallel claim based on the specific GMPs she cites. We observe that those circuit court cases approving of the use of GMPs as a basis for a parallel claim require that the plaintiff plead with greater specificity. *See, e.g., Bass*, 669 F.3d at 512 (concluding that a plaintiff must allege a failure to comply with GMPs and that this failure caused the injury). Moreover, these cases were resolved prior to any opportunity on the part of the plaintiff to obtain discovery. *See, e.g., Bass*, 669 F.3d at 506 (plaintiff’s case dismissed under rule 12(b)(6)); *Bausch*, 630 F.3d at 561 (concluding plaintiff did not need to specify which GMP was violated because they had no opportunity for discovery). Because Ms. Lamere had ample opportunity to discover whether any GMPs had been violated, we conclude that to survive a motion for summary judgment following discovery, Ms. Lamere is required to do more than merely cite two GMPs without explaining how the violation of

these GMPs occurred or how such a violation was causally related to the failure of the mechanical heart valve.

In the alternative, Ms. Lamere argues that she does not need to show a violation of federal law because there is no federal law specifically on point to preempt her state-law claim. Put another way, she argues that because no federal regulation requires or permits the mechanical heart valve to contain pores and crevasses, a state tort claim does not impose a requirement that is different from or in addition to the federal requirements for the device. We disagree.

In *Riegel*, the plaintiff similarly argued that “the duties underlying negligence, strict-liability, and implied-warranty claims are not pre-empted even if they impose ‘requirements, because general common-law duties are not requirements maintained with respect to devices.’” 552 U.S. at 327, 128 S. Ct. at 1009. The Supreme Court disagreed with this view, concluding that, “[n]othing in the statutory text [of the preemption statute] suggests that the preempted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general.” *Id.* at 328, 128 S. Ct. at 1010. “State tort law that requires a manufacturer’s [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.” *Id.* at 325, 128 S. Ct. at 1008. “Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation.” *Id.*

Ms. Lamere argues that her case is distinguishable from *Riegel* because her claim does not seek to “call into question the judgment of the manufacturer in marketing the

type of device at issue or the judgment of the FDA.” She argues that a general state-law duty not to distribute products with manufacturing flaws does not impose any requirements on St. Jude that are different from or in addition to federal requirements that are specifically applicable. But this argument ignores *Riegel*, which concluded that “[g]eneral tort duties of care . . . ‘directly regulate’ the device itself, including its design.” *Riegel*, 552 U.S. at 328-29, 128 S. Ct. at 1010. We conclude that imposing the state’s strict-liability rules on a PMA device would impose a general duty that would directly regulate the device itself, which would be a regulation that is different from the federal regulations applicable to the PMA device.

The PMA process does not guarantee that every device is safe: “As the Supreme Court aptly recognized, the premarket approval process is ultimately a cost-benefit analysis in which the potential health benefits are weighed against the potential risks.” *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008) (citing *Riegel*, 552 U.S. at 324-25, 128 S. Ct. at 1008). Therefore, because a state-law manufacturing-defect claim imposes a requirement that is different from or in addition to the existing federal requirements, Ms. Lamere’s manufacturing-defect claim is preempted by federal law.

### III.

St. Jude moved for attorney fees on appeal as a sanction, seeking just over \$17,000, pursuant to Minn. Stat. § 549.211. Sanctions may be imposed if the claims raised by Ms. Lamere are not “warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law.” *See* Minn. Stat. § 549.211, subd. 2(2). Because there is a federal-circuit split on

the issue of preemption and a lack of clarity regarding the interpretation of Minnesota's wrongful-death statute of limitations, we conclude that the appeal was meritorious, and we decline to award attorney fees. We therefore deny St. Jude's motion.

### **D E C I S I O N**

Minnesota's wrongful-death statute of limitations begins to run at the time the alleged wrongdoing occurs, not at the time the plaintiff's injury is discovered or becomes discoverable. Moreover, to sufficiently plead a parallel claim to avoid federal preemption under the MDA, a plaintiff must do more than merely raise the possibility of a violation of federal GMPs. Accordingly, we reverse the district court on the statute-of-limitations issue and affirm the district court on the issue of federal preemption and deny attorney fees.

**Affirmed in part and reversed in part; motion denied.**