SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

JACK RIEGER,

Plaintiff,

v.

MEDTRONIC MINIMED, INC., et al.,

Defendants.

Case No. 20STCV33401

The Honorable Stuart M. Rice,
Dept. 1

RULING ON SUBMITTED MATTER RE: MOTION FOR SUMMARY JUDGMENT AND/OR SUMMARY ADJUDICATION

Hearing Date: January 27, 2025

Moving Party: Defendants Medtronic MiniMed, Inc., MiniMed Distribution Corp., Medtronic, Inc., and Medtronic USA, Inc.

Responding Party: Jack Rieger, by and through Guardian ad Litem Cathy Giovenco

Ruling: **Motion for summary judgment and summary adjudication granted. Motion to seal granted.**

This is a single-plaintiff products liability action brought by plaintiff Jack Rieger, by and through his mother and guardian ad litem Cathy Giovenco (Plaintiff) against defendants Medtronic MiniMed, Inc., MiniMed Distribution Corp., Medtronic, Inc., and Medtronic USA, Inc. (collectively, Defendants or Medtronic) arising from allegedly defective insulin pumps and infusion sets. Specifically, Plaintiff alleges that he is an insulin-dependent diabetic, and while using a Medtronic MiniMed Paradigm Revel insulin pump, model MMT-723NAL (the Subject Pump), and

a compatible infusion set, one or both of the devices malfunctioned, causing him to suffer an unanticipated drop in blood glucose. As a result, while descending the stairs, Plaintiff fell over a railing to the ground and suffered severe injuries. Plaintiff brings causes of action for negligence, unfair competition (Bus. & Prof. Code § 17200 et seq.), and three causes of action for strict products liability. Defendants now move for summary judgment or, in the alternative, summary adjudication on the ground that the device in question was approved through the Food and Drug Administration's (FDA) pre-market approval (PMA) process, meaning that under 21 U.S.C. § 360k(a), any state requirements (including state tort law) which differ from federal requirements are preempted.

Legal Standards

The function of a motion for summary judgment or adjudication is to allow a determination as to whether an opposing party cannot show evidentiary support for a pleading or claim and to enable an order of summary dismissal without the need for trial. (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 843 (Aguilar).) "A party may move for summary adjudication as to one or more causes of action within an action, one or more affirmative defenses, one or more claims for damages, or one or more issues of duty, if the party contends that the cause of action has no merit, that there is no affirmative defense to the cause of action, that there is no merit to an affirmative defense as to any cause of action, that there is no merit to a claim for damages, as specified in Section 3294 of the Civil Code, or that one or more defendants either owed or did not owe a duty to the plaintiff or plaintiffs." (Code Civ. Proc. § 437c(f)(1).)

"A defendant or cross-defendant has met his or her burden of showing that a cause of action has no merit if the party has shown that one or more elements of the cause of action, even if not separately pleaded, cannot be established, or that there is a complete defense to the cause of action. Once the defendant or cross-defendant has met that burden, the burden shifts to the plaintiff or cross-complainant to show that a triable issue of one or more material facts exists as to the cause of action or a defense thereto. The plaintiff or cross-complainant shall not rely upon the allegations or denials of its pleadings to show that a triable issue of material fact exists but, instead, shall set forth the specific facts showing that a triable issue of material fact exists as to the cause of action or a defense

thereto." (Code Civ. Proc. § 437c(p)(2).)

Section 437c(c) "requires the trial judge to grant summary judgment if all the evidence submitted, and 'all inferences reasonably deducible from the evidence' and uncontradicted by other inferences or evidence, show that there is no triable issue as to any material fact and that the moving party is entitled to judgment as a matter of law." (*Adler v. Manor Healthcare Corp.* (1992) 7 Cal.App.4th 1110, 1119.) "The function of the pleadings in a motion for summary judgment is to delimit the scope of the issues; the function of the affidavits or declarations is to disclose whether there is any triable issue of fact within the issues delimited by the pleadings." (*Juge v. County of Sacramento* (1993) 12 Cal.App.4th 59, 67, citing *FPI Development, Inc. v. Nakashima* (1991) 231 Cal.App.3d 367, 381-382.)

Courts "liberally construe the evidence in support of the party opposing summary judgment and resolve doubts concerning the evidence in favor of that party." (*Dore v. Arnold Worldwide, Inc.* (2006) 39 Cal.4th 384, 389.) To establish a triable issue of material fact, the party opposing the motion must produce substantial responsive evidence. (*Sangster v. Paetkau* (1998) 68 Cal.App.4th 151, 166.) "Supporting and opposing affidavits or declarations shall be made by a person on personal knowledge, shall set forth admissible evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated in the affidavits or declarations." (Code Civ. Proc. § 437c(d).) "A court generally cannot resolve questions about a declarant's credibility in a summary judgment proceeding …unless admissions against interest have been made which justify disregard of any dissimulation." (*AARTS Productions, Inc. v. Crocker National Bank* (1986) 179 Cal.App.3d 1061, 1065 (*AARTS Productions*).)

Requests for Judicial Notice

I. Defendants' Request

Defendants request judicial notice of the following documents:

1. FDA Premarket Approval Re: P980022, Premarket Approval Database Listing for P98002 (CONTINUOUS GLUCOSE MONITORING SYSTEM) dated June 15, 1999 (Request for Judicial Notice (RJN) Ex. A);

2. FDA Premarket Approval Re: P980022/S013, Premarket Approval Database Listing for P980022 (PARADIGM REAL TIME SYSTEM) dated April 7, 2006 (RJN Ex. B);

3. FDA Premarket Approval Re: P980022/S031, Premarket Approval Database Listing for P980022 (PARADIGM REAL-TIME INSULIN INFUSION PUMPS) dated March 10, 2010 (RJN Ex. C);

4. Premarket Approval Database Listing for P980022 and all subsequent supplements (RJN Ex. D);

5. Correspondence from Medtronic MiniMed to the FDA dated October 3, 2005 (Rae Decl., Ex. A);

6. Correspondence from the FDA to Medtronic MiniMed dated April 7, 2006 (Rae Decl., Ex. B);

7. Correspondence from Medtronic MiniMed to the FDA dated August 5, 2008 (Rae Decl., Ex. C);

8. Correspondence from the FDA to Medtronic MiniMed dated March 10, 2010 (Rae Decl., Ex. D); and

9. Correspondence from the FDA to third parties dated September 23, 2011 concerning the citizen petition of Judith Duggan (Pack Decl., Ex. E).

Items 1-4, 6, 8, and 9 evidence official acts of an executive department of the United States, and so are subject to judicial notice under Evid. Code § 452(c). The Court **takes judicial notice** of them. Items 5 and 7 are Medtronic's own correspondence, apparently obtained from their own files. While these documents are seemingly properly authenticated and the Court may consider them as evidence on this motion, they do not appear subject to judicial notice, and the Court **does not take judicial notice** of them.

II. Plaintiff's Request

Plaintiff requests judicial notice of the following items:

1. The FDA's Summary of Safety and Effectiveness Data for Medtronic MiniMed's 530G insulin infusion systems approved under premarket approval application P120001 (Haverty Decl., Ex. 1);

2. The FDA's Summary of Safety and Effectiveness Data for Medtronic MiniMed's 630G insulin infusion systems approved under premarket approval application P150001 (Haverty Decl., Ex. 2); and

3. The FDA's Summary of Safety and Effectiveness Data for Medtronic MiniMed's 670G insulin infusion systems approved under premarket approval application P160017 (Haverty Decl., Ex. 3)

These documents all evidence official acts of the FDA, an executive department of the United States, in that they show the matters considered and determined with respect to the devices they pertain to. The Court therefore **takes judicial notice** of these documents, although not for the truth of their contents.

Evidentiary Objections

In unnumbered objections, Defendants object to Plaintiff's exhibits 2-11, 13, and 15-17 on the grounds that they are irrelevant to preemption, the sole basis for Defendants' motion. These objections are overruled. Plaintiff's argument in opposition is that the devices, components, or functionalities in question were not in fact PMA-approved, but entered the market through the 510(k) process, and are therefore not subject to preemption. The regulatory history of the devices in question and those preceding and following them is relevant to that argument, whether or not it is successful. The Court therefore **overrules** Defendants' objections in their entirety.

Motion to Seal

Defendants move to seal certain portions of and exhibits to the declarations of Eric Davila Lozada, Eric Larson, and Thomas Pack submitted in support of the motion. Per Mr. Larson, a Senior

Engineering Director of the Mechanical Hardware & Test Engineering team for Medtronic MiniMed, Inc., the materials to be sealed pertain to manufacturing information about Defendants' insulin pumps and litigation-related testing protocols for the pumps at issue. (Larson Declaration in Support of Motion to Seal, ¶¶ 4-7.) Mr. Larson declares:

> 8. These documents, and the information in these documents, is maintained by MiniMed in a secure fashion. MiniMed does not disclose the information publicly, to competitors, or to employees who do not need to know the information to perform their jobs. Making them public so MiniMed's competitors could access them would adversely impact MiniMed's business. … The Confidential Material is not generally known publicly or to MiniMed's competitors.
>
> 9. Public disclosure of the Confidential Material could have significant negative impact and cause significant harm to MiniMed if made public to MiniMed's competitors. Specifically, information on MiniMed's proprietary manufacturing processes could be used by competitors to obtain an advantage in the formulation of their own products and processes.
>
> 10. On the other hand, there is no public need for access to the Confidential Material. Rather, disclosure would only be meaningful to competitors and/or others in the field of medical device manufacturing and sales.

Based on these facts, the Court finds there is an overriding interest supporting sealing which overcomes the public right of access to the records, and that there is a substantial probability that interest will be prejudiced if the record is not sealed. The sealing is narrowly tailored and the most restrictive manner of achieving the overriding interest. The Court therefore grants the motion to seal and will direct the clerk to place the unredacted version under seal. Counsel for Defendant should submit a separate order granting the request to seal.

Discussion

I. Regulatory Background

Some preliminary discussion of the statutory landscape is appropriate. The Medical Device Amendments of 1976 (MDA) established three classes of medical device. (21 U.S.C. § 360c(a)(1).) The pump Plaintiff used, the 723 pump, is a Class III device. Class III devices are those for which lesser controls would be insufficient to "provide reasonable assurance of its safety and

effectiveness," and so they are subjected to the closest scrutiny, the pre-market approval (PMA) process. (21 U.S.C. § 360c(a)(1)(C), see also, generally, 21 U.S.C. § 360e(c) [PMA process].) "Despite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance,' …is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 477 (*Lohr*).)

There is a pertinent exception to the PMA process, which is that Class III devices which are "substantially equivalent" to pre-existing devices may be approved through a more limited form of review. (See 21 U.S.C. § 360e(b)(1)(B).) This is known as the 510(k) process, after the section of the original Food, Drug, and Cosmetic Act. (*Lohr, supra,* 518 U.S. at 478.)

> If the FDA concludes on the basis of the § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis (at least until the FDA initiates the PMA process for the underlying pre–1976 device to which the new device is "substantially equivalent"). The § 510(k) notification process is by no means comparable to the process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. [Citation.] As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." [Citations.]
> (*Id.* at 478-479.)

Lohr discusses the § 510(k) process and Congress's intentions:

> Congress anticipated that the FDA would complete the PMA process for Class III devices relatively swiftly. But because of the substantial investment of time and energy necessary for the resolution of each PMA application, the ever-increasing numbers of medical devices, and internal administrative and resource difficulties, the FDA simply could not keep up with the rigorous PMA process. As a result, the § 510(k) premarket notification process became the means by which most new medical devices—including Class III devices—were approved for the market. In 1983, for instance, a House Report concluded that nearly 1,000 of approximately 1,100 Class III devices that had been introduced to the market since 1976 were admitted as "substantial equivalents" and without

> any PMA review. [Citation.] This lopsidedness has apparently not evened out; despite an increasing effort by the FDA to consider the safety and efficacy of substantially equivalent devices, the House reported in 1990 that 80% of new Class III devices were being introduced to the market through the § 510(k) process and without PMA review.
> (*Lohr, supra,* 518 U.S. at 479.)

In 2005, more than 3,000 devices were approved under § 510(k), and only 32 through PMA. (*Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 317 (*Riegel*).)

II. Preemption for PMA-Approved Devices

The MDA contains a provision establishing express federal preemption of state requirements for devices which differ from federal requirements:

> (a) General rule
> Except as provided in subsection (b), 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).)

Subsection (b) of that section permits the Secretary of Health and Human Services to exempt otherwise-preempted state requirements, which has not happened here. (See 21 U.S.C. § 360k(b).)

The U.S. Supreme Court has held that 510(k) review does not impose federal "requirements" on the device, and so does not create preemption. (*Lohr, supra,* 518 U.S. at 493-494.) 510(k) review is intended to permit manufacturers to market competing equivalents of already-existing devices, "maintain[ing] the status quo with respect to the marketing of existing medical devices and their substantial equivalents." (*Id.* at 494.) "That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." (*Ibid.*) This is because "the 510(k) process is focused on equivalence, not safety." (*Id.* at 493.)

The PMA process, on the other hand, does impose "requirements" on the approved device within the meaning of the MDA. (*Riegel, supra,* 552 U.S. at 322.)

> Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it is federal safety review. Thus, the attributes that Lohr found lacking in § 510(k) review are present here. While § 510(k) is " 'focused on equivalence, not safety,' " [citation], premarket approval is focused on safety, not equivalence. While devices that enter the market through § 510(k) have "never been formally reviewed under the MDA for safety or efficacy," …the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness, § 360e(d). And while the FDA does not "'require'" that a device allowed to enter the market as a substantial equivalent "take any particular form for any particular reason," [citation], the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.
> (*Id.* at 322-323.)

In *Riegel*, the Supreme Court reiterated its conclusion in *Lohr* that "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." (*Riegel, supra,* 552 U.S. at 323-324, citing *Lohr, supra,* 518 U.S. at 512.) However, the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." (*Id.* at 330, citing *Lohr, supra,* 518 U.S. at 495.)

III. Application of Preemption Framework to Plaintiff's Causes of Action

"In *Riegel*, the United States Supreme Court established a two-step framework for determining whether section 360k(a) expressly preempts a state law claim. First, the FDA must have established 'requirements' applicable to the particular medical device at issue. (*Riegel, supra,* 552 U.S. at p. 321, 128 S.Ct. 999.) The premarket approval requirements applicable to class III medical devices satisfy this first prong. (*Id.* at pp. 322–323, 128 S.Ct. 999.) Next, state law claims are preempted if they impose requirements that relate to safety and effectiveness and are 'different from, or in addition to' the requirements under federal law." (*Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413, 423-424.)

a. Whether Requirements were Established as to the 723 Pump

Plaintiff was injured while using a MMT-723 insulin pump. (Defendants' Undisputed Material Fact (UF) 1.) On August 15, 2008, MiniMed submitted the MMT-723 pump for approval as a supplement to PMA application 980022, and the FDA approved the supplement on March 10, 2010.[1] (UF 3, 5.) PMA application 980022 pertains to the Continuous Glucose Monitoring System, also known as the Paradigm System, originally approved on June 15, 1999. (Defendant's Request for Judicial Notice (RJN), Ex. A.) The 723 pump was a successor to the 522/722 pump, which received PMA as part of a supplement to application 980022 in April 2006. (UF 6.) On September 23, 2011, the FDA specifically rejected a citizen petition that requested the approval of the 522 pump be limited to "the ability of the pump to accept data from the sensor and the ability for the sensor to communicate directly to the pump, and …not…to the pump itself." (UF 7; Pack Decl., Ex. E.) In so doing, the FDA stated that "FDA approved the PMA supplement for the Paradigm System, including both the 522 pump and the Guardian RT sensor, on April 17, 2006." (*Ibid.*) Put simply, the FDA considered its 2006 approval of the PMA supplement to include both the pump and the system as a whole. Therefore, the 723 pump received PMA review in 2010, and 21 U.S.C. § 360k(a) would preempt any requirements that differ from the requirements imposed by the PMA.

Plaintiff contends that the insulin-delivering functionality of the 723 pump (that is, the functionality that is alleged to have harmed Plaintiff) should be considered separately from the glucose-monitoring functionalities of the pump, and that under that analysis, the insulin-delivering functionality of the 723 pump has never undergone PMA review. To understand this contention, the Court will discuss the history of the 723 pump, as Plaintiff has laid out.

In brief, the 723's predecessor, the 522/722, contained a glucose-monitoring functionality "equivalent to the Guardian® RT (approved on July 18, 2005 under P980022/S011) in that it has the ability to display glucose measurements in real time, and incorporates alarms based on glucose measurements[,]" as well as an insulin-delivering functionality with "the same functions currently

[1] Defendants' and Plaintiff's entries in the separate statement both give the year as 2020, but this appears to be a typo. (See Rae Decl., Ex. D [March 10, 2010.])

available in the Paradigm MMT-515/715." (See Plaintiff's Exhibit 11, p. MDT-BRACP-0040873.) When used without the glucose-monitoring functionality, "the capabilities of these pumps [i.e. the 522 and 722] will be identical to those of the currently cleared MMT-515 and 715 pumps." (*Id.,* p. MDT-BRACP-0040888.) Those MMT-515/715 pumps, meanwhile, had entered the market through the 510(k) process, not through PMA, and was approved after only two months. (See Plaintiff's Ex. 10.) When the 523/723 pump was submitted for PMA to replace the 522/722, Medtronic stated that "[t]he indication for use for these new pump models is identical to that of the previously approved MMT-522, MMT-722, MMT-522K and MMT-722K[,]" that "[t]here have been no changes to the hardware of the Paradigm REAL-Time insulin infusion pumps in association with creating these new pump models[,]" but rather, that the new pumps "utilize updated application software that incorporates enhancements to the glucose monitoring and insulin delivery features." (Plaintiff's Ex. 13, p. MDT-BRACP-017801.)

In other words, the 515/715 pumps were approved under 510(k) review, not PMA review, the 522/722 pumps were just the 515/715 pumps with glucose-monitoring functionality added to the 515/715 hardware (and if used without that added functionality, functioning identically to the 515/715), and the 523/723 pumps were just the 522/722 pumps with software updates. Therefore, per Plaintiff, it is only the glucose-monitoring functionality which should receive PMA preemption, and not the 523/723 pump as a whole.

In support of this position, Plaintiff presents the case of *Shuker v. Smith & Nephew, PLC* (3d Cir. 2018) 885 F.3d 760 (*Shuker*), a case from the Third Circuit. In *Shuker,* the plaintiff patient was injured by a hip replacement system wherein "[s]ome components replaced the top of Mr. Shuker's thighbone …with a metal head, metal sleeve, and a stem connecting the metal head to the thighbone, while another component rested on his hip socket…." (*Id.* at 768.) A metal liner in the hip socket connected with the metal head on the thighbone, and this metal-on-metal connection created debris that traveled into his body. (*Id.* at 768-769.) The metal liner had gone through PMA as one part of a different system of implants and was being used off-label in the Mr. Shuker's hip replacement system. (*Ibid.*) The District Court found that the plaintiff's negligence, strict liability,

and warranty claims against the manufacturer were expressly preempted because "'the heart of each of [the plaintiffs'] claims' challenged the safety and effectiveness of the R3 metal liner, which had received premarket approval, was therefore subject to federal requirements, and, hence, gave [the manufacturer] the benefit of express preemption." (*Id.* at 769.) The plaintiffs appealed.

Before the Third Circuit, the plaintiffs argued that the "device" that must be considered was the entire system in Mr. Shuker's body, the PMA-approved metal liner together with the other components being combined off-label, a combination the FDA had never approved. (*Shuker, supra,* 885 F.3d at 772.) The Third Circuit rejected that approach, agreeing with the manufacturer and the FDA (as amicus curiae) that "analysis at the component level is the only way to harmonize various provisions of the statute." (*Ibid.*) Because "the negligence, strict liability, and breach of implied warranty claims asserted…would impose non-parallel state law requirements [,]" they were expressly preempted, and the Third Circuit affirmed. (*Id.* at 775.)

Plaintiff accurately cites to and partially relies on Shuker in support of its position. *Shuker* discusses the regulatory framework as follows:

> The Federal Food, Drug, and Cosmetic Act defines "device" to mean not simply a finished "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," **but also "any component, part, or accessory"** of that article. 21 U.S.C. § 321(h). Codified in 1938 with the original Act, this definition has always provided that the term "device" includes **"components, parts, and accessories,"** mirroring the definition for "drug" immediately preceding it, which was and is defined to include "articles intended for use as a component" of a drug. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 201(g), (h), 52 Stat. 1040, 1041 (1938) (codified as amended at 21 U.S.C. § 321(g), (h)). The implementing regulations, at least for quality control purposes, also describe "[c]omponent" to include "any raw material, substance, **piece, part, software, firmware,** labeling, **or assembly** which is intended to be included as part of the finished, packaged, and labeled device." 21 C.F.R. § 820.3(c).
> [¶]
> …[T]he FDA, "the federal agency to which Congress has delegated its authority to implement provisions of the Act," *Lohr,* 518 U.S. at 496, 116 S.Ct. 2240, also takes the position that because "the definition of 'device' encompasses ... premarket-approved ... system[s], and each of the 'component[s], part[s], [and] accessor[ies]' of these devices," **the relevant device for preemption purposes must be evaluated at the component level.** FDA Amicus Br. 7 (all but first alteration in original)

> (quoting 21 U.S.C. § 321(h)).11 And, contrary to the Shukers' argument that "[t]he FDA reviews ... *systems*, not individual ... *components*," Appellant's Br. 17, the Medical Device Amendments direct the FDA, "where necessary to provide reasonable assurance of ... safe and effective performance," to establish performance standards for device components, 21 U.S.C. § 360d(a)(2)(B)(i), while the FDA's regulations require manufacturers of finished devices, if "deviations from device specifications could occur as a result of the manufacturing process," to monitor and control "component ... characteristics during production." 21 C.F.R. § 820.70(a)(2). What's more, just like manufacturers of finished devices, manufacturers of "components or accessories" are subject to device registration and reporting requirements. Id. §§ 803.3(l)(3), 806.2(h)(3), 807.20(a)(6); see id. §§ 803.50, 806.10. *See generally* 21 U.S.C. §§ 360(b), (j), 360i(a)(1), (g)(1).
> (*Shuker, supra,* 885 F.3d at 772-773, bold added.)

Under the *Shuker* approach, the insulin-dispensing apparatus would appear to fall within the definition of a "device," as it is some combination of components, pieces, parts, software, firmware, and/or assembly which is separate from the glucose-monitoring apparatus. As discussed above, the insulin-dispensing function of the 723 pump can apparently be used without the glucose-monitoring function, such that the pump functions identically to the earlier 515/715 pump.

Plaintiff's argument that the insulin-dispensing apparatus never underwent the PMA process does not create a disputed issue of material fact. The FDA expressly rejected a citizen petition that requested the FDA to take the position that its approval of the 522/722 pump, a predecessor to the 723 pump, was "limited solely to the ability of the pump to accept data from the sensor and the ability for the sensor to communicate directly to the pump" and "[did] not extend to the pump itself." (Pack Decl., Ex. E, p. 1.) In reliance on this position by the FDA, at least two courts have found similar claims involving the 522/722 to be preempted. (See *Duggan v. Medtronic, Inc.* (D. Mass. 2012) 840 F.Supp.2d 466, 472 (*Duggan*) ["To the extent there was any ambiguity about the scope of the approval letter, this rejection of the Citizen Petition is the cherry on the icing."]; *Bentzley v. Medtronic, Inc.* (E.D. Pa. 2011) 827 F.Supp.2d 443, 451 (*Bentzley*) [citing petition and holding that "Plaintiff failed to raise a genuine issue of material fact whether the MMT–522 System, including the pump, received premarket approval."])

Plaintiff argues that *Bentzley* has been implicitly disapproved by the Third Circuit's *Shuker*

opinion, which was issued seven years later. The *Bentzley* District Court opinion rested on two points: 1) that the 522/722 pump had received PMA as part of the Continuous Glucose Monitoring System; and 2) that the plaintiff's argument for a component-level analysis was "without legal support." (See *Bentzley, supra,* 827 F.Supp.2d at 451-452.) *Shuker*'s component-level analysis might disturb the latter ground, but not the former.

It is here that *Shuker*'s factual setting is particularly relevant to the analysis. In *Shuker,* the issue was a device (the metal liner) extracted from one PMA-approved system (the Birmingham Hip Resurfacing System, or BHR, and specifically the R3 Metal on Metal Cups) for use in one which was not PMA-approved (a total hip replacement). (*Shuker, supra,* 885 F.3d at 768-769.) The District Court opinion relied on by the Third Circuit provides pertinent detail:

> [I]n April 2007, Defendants filed a PMA application supplement, seeking approval for a line extension to the BHR System consisting of a modular version of the BHR cup. [Citation.] The modular BHR cups, referred to as R3 Metal on Metal Cups, **consist of an R3 acetabular shell made of titanium alloy and an R3 metal liner made of cobalt-chromium alloy.** [Citation.] The PMA supplement represented that the metal-on-metal articulation of the BHR System with the modular cups would be unchanged from that of the System with the one-piece cups the FDA had previously approved. [Citation.] On November 13, 2008, the FDA approved the PMA supplement and granted Defendants permission to distribute the BHR System with the modular cups.
> (*Shuker v. Smith & Nephew PLC* (E.D. Pa. Mar. 31, 2015, No. 13-6158) 2015 WL 1475368, p. 3, emphasis added.)

In other words, the FDA approved, through the PMA process, a device consisting of two distinct components, the metal shell and the metal liner. The metal liner was not apparently separately approved. Even so, the Third Circuit agreed with the FDA's position as amicus curiae that the liner "received premarket approval as part of the Birmingham Hip Resurfacing System; and that premarket approval 'imposed requirements on the liner with respect to its composition, dimensions, and labeling, among other specifications'" supporting preemption. (*Shuker, supra,* 885 F.3d at 774.) Applying *Shuker*'s reasoning, the 723 pump's insulin-delivery functions (i.e. a "device" in its own right under *Shuker*'s component-level approach) received PMA as part of the pump's March 10, 2010 approval process.

Plaintiff contends that nonetheless, the insulin-delivery functions of the 723 pump never received the rigorous scrutiny required for PMA. Plaintiff offers no authority for the idea that courts may review the rigor of the FDA's approval process and except devices or components from the scope of preemption if the FDA did not do enough. *Hafer v. Medtronic, Inc.* (W.D. Tenn. 2015) 99 F.Supp.3d 844 does not so provide, but simply states that "[t]he Court will not go as far as to say that every component under a PMA is automatically covered, but where, as in here, it is the primary component that received the majority of the FDA's attention and balancing of interests, the Court finds no issue with finding it subject to the PMA." (*Id.* at 858.) Given that the *Hafer* court did find preemption to apply, any suggestion that components which do not "receive the majority of the FDA's attention" would not receive preemption is pure dicta and would not be sufficient to support the relief Plaintiff seeks.

By way of evidence, Plaintiff presents the following: The 515/715 pump was approved through the 510(k) process, like its predecessors. (Plaintiff's Additional Material Facts (AF) 10-20.) Medtronic then proposed to incorporate the 515 pump into the 522/722 system, in essence adding the "same functions currently available in the Paradigm MMT-515/715" to the system. (AF 21-22.) Medtronic represented that the sensor monitoring functionality that would be added to the 515/715 pump to create the 522/722 pump was optional, and that if that functionality were not enabled, the 522/722 pump and the 515/715 pump would have identical capabilities. (AF 23-24.) The 522/722 pump was approved after six months. (AF 25.) The only changes to the 522/722 pump to create the 523/723 pump were software changes, leaving all hardware aspects the same. (AF 27.) Medtronic submitted no clinical data to support the 523/723 pump application for PMA. (AF 28.) When Medtronic submitted new PMA applications for later pumps (the 530G and 670G) that did have interaction between insulin-dispensing and glucose-monitoring, Medtronic submitted clinical data and human factors testing. (AF 29-32.)

None of these facts, even if undisputed, support an inference that the FDA did not perform rigorous or sufficient review of the 522/722 or 523/723 pumps or their components before granting

PMA. Plaintiff simply urges the Court to infer that because the 515/715 pump reached market through the 510(k) process, and since Medtronic told the FDA that the 522/722 pump had the same pump functionality, the FDA did not rigorously review that functionality. The absence of clinical data in the 522/722 pump application assumes that clinical data is always required, or would have been required in this case, contentions which Plaintiff fails to support with evidence or argument. Likewise, because the review of the 523/723 pump was completed in only six months, Plaintiff asks the Court to infer that was not enough time. There is no evidence on which to base that inference.

Plaintiff presents no evidence of what the FDA's review of the 522/722 or 523/723 pumps actually entailed, nor any expert testimony concerning whether the FDA acted reasonably or typically in its review. There is nothing the Court can rely on in determining what the minimum standard of PMA review ought to be, and whether the FDA's review of the pertinent pumps fell below that level. Mere difference between the review of the 522/722, the 523/723, the 530G, and the 670G, standing alone, does not suffice. The Court would simply be speculating were it to hold that the FDA did not sufficiently review the 522/722 or 523/723 pumps. "When opposition to a motion for summary judgment is based on inferences, those inferences must be reasonably deducible from the evidence, and not such as are derived from speculation, conjecture, imagination, or guesswork." (*Advent, Inc. v. National Fire Ins. Co. of Pittsburgh, PA* (2016) 6 Cal.App.5th 443, 459, quoting *Joseph E. Di Loreto, Inc. v. O'Neill* (1991) 1 Cal.App.4th 149, 161.)

For the foregoing reasons, Defendant has established the first prong of the *Riegel* analysis.

b. Whether Plaintiff's Causes of Action Impose "Different" Requirements

Plaintiff's complaint also contains a cause of action for violation of the Unfair Competition Law (UCL, Bus. & Prof. Code § 17200 et seq.). (Complaint, ¶¶ 125-130.) As predicate violations, Plaintiff alleges:

> Defendants have violated a number of Federal regulations, including the FDCA, MDA, CGMP, and device-specific PMA specifications, including failure to conform their devices to regulations and specifications, failure to discover dangers in their devices, failure to report dangers in their

> devices, failure to investigate reports, negligently marketing and promoting their devices as safe, and failures to warn, among others. These acts and others, including Defendant's negligent and intentional decisions to manufacture their devices in violation of laws and regulations were and are likely to mislead Plaintiff Rieger, constituting unfair business practices under section 17200, et seq.
> (Complaint, ¶ 127.)

Plaintiff does not dispute that the 723 pump Plaintiff was using when he was injured complied with the design and manufacturing requirements imposed by its PMA. (UF 9-12.) Necessarily then, Plaintiff's causes of action seek to impose different requirements than those imposed by the FDA. Common-law duties, such as those underlying negligence and strict liability, seek to impose requirements different from those required by the PMA process, and so are preempted. (*Riegel, supra,* 552 U.S. at 323-324.) Neither Plaintiff's complaint nor Plaintiff's opposition papers identify any pertinent statutes that Defendants violated. To the extent that Plaintiff's UCL claim is seeking to enforce federal legal requirements, the claims would be impliedly preempted. As observed in *Glennen v. Allergan, Inc.* (2016) 247 Cal.App.4th 1 (*Glennen*):

> Implied preemption under the MDA bars claims seeking to enforce an exclusively federal requirement that is not grounded in traditional state tort law. Claims not tied to state law tort duties are essentially private actions to enforce the FDCA and are barred by 21 United States Code section 337(a), a provision authorizing the federal government to enforce the MDA. "The FDA is responsible for investigating potential violations of the FDCA, and the Act provides the agency with a range of enforcement mechanisms, such as injunction proceedings, civil and criminal penalties, and seizure. [Citation.] Although citizens may petition the FDA to take administrative action, [citation], private enforcement of the statute is barred: 'all such proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States.'" [Citation.]
> (*Id.* at 10-11; see also *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 343 [claims based on company's alleged failures to make disclosures to the FDA during approval process were impliedly preempted].)

As Plaintiff identifies no such federal requirements as the predicate for the UCL claim, the claim necessarily seeks to enforce legal requirements different from those of the FDA. Because the negligence and strict liability claims also seek to impose different requirements than those of the PMA process, they are all expressly preempted. The Court is sensitive to Mr. Rieger's severe

injuries and does not reach this conclusion lightly. The decrees of *Riegel* are nonetheless clear. The motion for summary judgment must therefore be granted.

Conclusion

For the foregoing reasons, the motion for summary judgment and summary adjudication is **granted**. Defendants to lodge a proposed judgment, an order granting the motion to seal and give notice. In view of this ruling, all future dates previously set are vacated.

DATED: January 28, 2025

Stuart M. Rice / Judge

THE HONORABLE STUART M. RICE
JUDGE OF THE SUPERIOR COURT