IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CHRISTOPHER URQHART, Individually, and as Widower of NANCY JUNE URQHART, deceased, and AMY EHLERS, Individually, and as daughter of NANCY JUNE URQHART, deceased,	)	
Plaintiffs,	)	
v.	)	Case No. 4:24-cv-01465-SRC
ABIOMED, INC.,	)	JURY TRIAL DEMANDED
Defendant.	)	

DEFENDANT ABIOMED, INC.'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ITS MOTION FOR JUDGMENT ON THE PLEADINGS

Plaintiffs' Opposition demonstrates counsel's misunderstanding of what constitutes a parallel claim. Nowhere in the Complaint do Plaintiffs even attempt to allege that Abiomed violated the FDA's mandates for the Impella 5.5, much less state what the alleged defect with the device was or how such defect purportedly caused Mrs. Urquhart's alleged injuries—all of which is required to state a claim capable of surviving preemption. Abiomed's Motion for Judgment on the Pleadings should be granted and Plaintiffs' request for the opportunity to re-plead should be denied, for the following reasons:

First, neither their Complaint nor their Opposition allege how the Impella 5.5 deviated from Abiomed's intended (and FDA-approved) design. Despite Plaintiffs' insistence that they pled a manufacturing defect claim, their Complaint does not articulate what federal requirement Abiomed purportedly violated or how it did so, much less articulate what the "manufacturing defect" actually was. The Complaint alleges only that "the lead" of the Impella 5.5 "was

improperly manufactured," but offers no further factual allegations or support for that conclusory statement. *See* Compl. ¶ 13. Nor does it allege how this purported defect caused injury to Mrs. Urquhart. Every possible theory of product liability that could be gleaned from the Complaint relates to the safety of the Impella 5.5 and is preempted by federal law and binding U.S. Supreme Court case law because the device received pre-market approval ("PMA") from the FDA. Once a device has received PMA, the manufacturer cannot change any aspect of the device affecting safety or efficacy without FDA approval. Plaintiffs' state law claims would impose on Abiomed obligations that differ from, or add to, federal requirements. To survive preemption, Plaintiffs face the rigorous burden of stating a parallel claim, which they have neither done nor shown they are able to do.

Second, even if Plaintiffs' Complaint had included the new allegations set forth in their Opposition, they would still not be able to articulate what federal requirement Abiomed purportedly violated or how it did so. Indeed, of the six purported "recalls" listed for the first time in Plaintiffs' Opposition, only one even involves the device at issue. With respect to that sole "recall" (which was *not* a removal of the device from the field), the recall notice shows, on its face, that it is wholly unrelated to Plaintiffs' claims: the recall pertains to the Impella 5.5 being used in patients undergoing a different procedure than the one Mrs. Urquhart is alleged in the Complaint to have undergone. Moreover, that "recall" applied to all Impella 5.5 devices that were manufactured *as designed*. Any purported parallel "manufacturing defect" claim premised on that recall would also fail as it is actually a design defect claim preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. 360k. Thus, even if Plaintiffs were permitted to amend

their Complaint to include these new "recall" allegations,[1] their claim would still be preempted because it necessarily seeks to impose requirements for the design and manufacture of the device that are "different from, or in addition to" federal requirements.

I. Plaintiffs' Claims Are Preempted By Federal Law.

Plaintiffs' claims are preempted by the MDA because they necessarily seek to impose different requirements for the Impella 5.5 than those mandated by the FDA. *See In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (hereafter "*In re Medtronic*") (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323-24 (2008); 21 U.S.C. § 360k(a)). Plaintiffs have not demonstrated otherwise.

Contrary to Plaintiffs' belief, there is no "presumption against preemption" in the context of medical devices. *See* Doc. 34 (Pls.' Opp.) at 5. Instead, the MDA provides express preemption *for* medical devices. *See Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (citing 21 U.S.C. § 360k(a) and noting that Congress intended express preemption for medical devices); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA [MDA] leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with medical device provisions."); *and Missouri Bd. of Examiners for Hearing Instrument Specialists v. Hearing Help Exp., Inc.*, 447 F.3d 1033, 1035 (8th Cir. 2006) (contrasting the express and undeniable preemption provided in the MDA with instances "without clear congressional intent there is a general presumption against finding *implied* preemption.") (emphasis added).

1. Plaintiffs cannot, however, now amend their Complaint, since the pleadings are closed and this is a Motion for Judgment on the Pleadings under Rule 12(c).

In *Riegel*, the Court rejected the dissent's reliance on such a presumption, because "the text of [§ 360k(a)]" plainly evidences Congress's intent to displace "the tort law of 50 States." *Riegel*, 552 U.S. at 326. The Supreme Court has reiterated that where "the statute contains an express preemption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Puerto Rico v. Franklin California Tax-Free Trust*, 579 U.S. 115, 125 (2016) (internal quotation marks and multiple citations omitted). Plaintiffs do not dispute that the MDA contains an express preemption clause, and nothing in Plaintiffs' Opposition changes the significance of the express preemption clause. For all of Plaintiffs' discussion of an "anti-preemption presumption," they still agree that *Reigel* governs. *See, e.g.*, Doc. 34 at 5 (citing *Reigel*). And the cases they cite do not salvage the shortcomings of their Complaint—namely, their failure to allege any parallel state law claim for a manufacturing defect.

Of the three preemption cases cited by Plaintiffs that address *Reigel*, two actually declined to find that the parallel claim exception applied. In *McLaughlin v. Bayer Corporation*, the court found that "[p]laintiffs [had] not specified which federal requirements ha[d] been violated by each alleged incident of negligent conduct," and, as a result, it was "unable to discern whether [plaintiffs'] state law negligent manufacture claim actually rest[ed] on violations of federal requirements" such that it could be considered a parallel claim. 172 F. Supp. 3d 804, 835 (E.D. Pa. 2016). Similarly, in *De La Paz v. Bayer Healthcare LLC*, the court dismissed the plaintiff's manufacturing claim as preempted under *Reigel* because she failed to allege the existence of any manufacturing defect and "fail[ed] to allege a causal link between [any defect] and her injuries." 159 F. Supp. 3d 1085, 1094–95 (N.D. Cal. 2016). Indeed, only one of Plaintiffs' cases citing *Riegel*, *Hofts*, even found the parallel claim exception applied, and only after the court noted "it

[was] clear" the plaintiff "bases his tort claims on allegations that the [defendant] failed to meet the FDA's requirements"—a fact pattern that does not exist in Plaintiffs' Complaint. *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 836 (S.D. Ill. 2009) (finding a parallel claim exception applied only because the plaintiff based his claims on specific failures of defendant's product to meet federal requirements).[2]

Here, Plaintiffs' claims closely resemble those found to be preempted in *De La Paz*. Like *De La Paz*, Plaintiffs "offer no description" of the Impella 5.5's supposed defect. 159 F. Supp. 3d at 1095. Additionally, similar to the plaintiffs in *De La Cruz*, Plaintiffs allege causation with only "conclusory allegations that the alleged irregularities caused her injuries." *Id.*; *see also* Compl. ¶ 15 ("As a result of the complications caused by the Impella, Plaintiff-Decedent died on September 12, 2024."). This type of "conclusory allegation is not entitled to the presumption of truth on a motion to dismiss." *De La Paz*, 159 F. Supp. 3d at 1095 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009)). As a result, Plaintiffs' Opposition merely affirms the shortcomings of their Complaint—they do not allege any of the required elements to sustain a parallel claim or avoid *Reigel* preemption. Their Complaint fails, and Abiomed's motion must be granted.[3]

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2. It is also worth noting that *Hofts* was issued shortly after *Reigel* was decided, and its deferential reasoning was later rejected by the Eighth Circuit. *Compare Hofts*, 597 F. Supp. 2d at 838 (rejecting requirement that a plaintiff identify violations of FDA requirements "with sufficient specificity") with *In re Medtronic*, 623 F.3d at 1210 (claims preempted where "plaintiffs failed to identify any specific federal requirement in the PMA approval" that was violated).

3. Even if Plaintiffs could be permitted to amend their Complaint, because they revealed in their Opposition the new "allegations" upon which they would base their proposed manufacturing defect claim (which show such claim is still preempted), distinct from *De La Paz*, Plaintiffs' amended Complaint would still fail.

II. Plaintiffs Do Not Allege Any Parallel Claim That Survives Preemption.

Exceptions to preemption under the MDA are rare, and they must be set forth on the face of the complaint. Claims asserted under state laws that "parallel" federal law and do not add to or vary from the federal requirements for the device are not preempted. *Riegel*, 552 U.S. at 330. First, "[t]o properly allege parallel claims, the complaint must set forth facts pointing to specific [federal] requirements that have been violated." *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 986 (E.D. Mo. 2014) (quoting *Wolicki-Gables*, 634 F.3d at 1301); *see also Hilyard v. Medtronic, Inc.*, 21 F. Supp. 3d 1012, 1019 (E.D. Mo. 2014) (same). Second, the plaintiff must "set out how [the device] was manufactured outside of the specifications of the PMA and allege[] the ways that those defects caused his device to fail and injure him." *Welz v. Boston Scientific Corp.*, No. 4:24-cv-820, 2024 WL 4252817 at *4 (E.D. Mo. Sept. 20, 2024) (plaintiff must "do[] more than simply allege that [Defendant] has violated unspecified or generic federal regulations").

Plaintiffs rely upon *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) for the proposition that their "only burden" in pleading parallel state law claims is "to put forth facts that make the claim plausible on its face." Doc. 34 at 4. Those decisions, however, specify that only a complaint stating a plausible claim for relief survives a motion for judgment on the pleadings. *Iqbal,* 129 S.Ct. at 1950 (citing *Twombly,* 550 U.S. at 556). Plaintiffs' Complaint fails in that regard; they neglect to mention that their Complaint pleads no facts to support such a claim. Plaintiffs' Complaint is void of any allegations that Abiomed violated the requirements set forth by the FDA for the Impella 5.5. Instead, Plaintiffs merely state that the Impella 5.5 "was unreasonably dangerous as the lead of the [I]mpella, which was supposed to release after the surgical procedure was completed, was improperly manufactured." *See* Compl.

¶ 13.[4] Plaintiffs do not even allege whether the Impella 5.5 "lead" actually did or did not "release[,]" much less what happened as a result of the same. As this Court has held, a district court "is not required to divine the litigant's intent and create claims that are not clearly raised, and it need not conjure up unpled allegations to save a complaint." *Ginsburg v. InBev NV/SA,* 649 F.Supp.2d 943, 946 (E.D. Mo. 2009) (Hamilton, J.) (granting judgment on the pleadings). Plaintiffs argue their conclusory allegation that the Impella 5.5 was "unreasonably dangerous" is tantamount to alleging a violation of federal requirements. But well-pleaded facts, not legal theories or conclusions, determine the adequacy of the complaint in the face of a Motion for Judgment on the Pleadings. *See, e.g., Edwards v. McSwain,* 2018 WL 4679735 at *3 (E.D. Mo., Sept. 28, 2018) (Fleissig, J.) (granting judgment on the pleadings). Moreover, Plaintiffs' allegation is patently false.

Because Plaintiffs do not identify any federal requirement applicable to the Impella 5.5, much less allege that any such requirement was violated by Abiomed, their claim that the device was defective is expressly preempted. *Zaccarello v. Medtronic, Inc.*, 38 F. Supp. 3d 1061, 1066-67 (W.D. Mo. 2014) (finding plaintiff's manufacturing defect claim expressly preempted); *see also Blankenship*, 6 F. Supp. 3d at 986 (E.D. Mo. 2014) (same). Plaintiffs' claims, as pled, would permit a finding that the Impella 5.5 was defective even if Abiomed fully complied with the FDA's requirements for the device. And even if true, that allegation still would not surmount the pleading requirements for parallel claims. *Dorman v. Bayer Corp.*, No. 4:16CV601 HEA, 2016 WL

4. Seeing as their three-page Complaint does not set forth any allegations sufficient to state a parallel claim, Plaintiffs list seven theories of liability in their Opposition with proposedly similar "federal requirements" and "Missouri Law" in an attempt to show such legal theories could "plausibly" parallel federal requirements. *See* Pls. Opp. at 6-7. But, Plaintiffs ignore the fact that, while it is perhaps plausible a plaintiff *could* allege facts that comprise a parallel claim sufficient to evade preemption based on Missouri law, Plaintiffs have not done so. *See* Doc. 34 at 6-7.

7033765, at *3 (E.D. Mo. Dec. 2, 2016) (citing *Wolicki-Gables*, 634 F.3d at 1301 ("To properly allege parallel claims, the complaint must set forth facts pointing to specific [federal] requirements that have been violated." (internal quotations and citation omitted))).

III. Any Amendment of Plaintiffs' Complaint Would Be Futile and Leave to Amend Should Be Denied.

Plaintiffs seek denial of Abiomed's Motion, but alternatively request leave to amend their Complaint and conduct discovery. Doc. 34 at 7. Plaintiffs' request, in the context of the Motion for Judgment on the Pleadings, should be rejected by this Court. Their claim(s) is preempted by the MDA, and Plaintiffs offer no additional factual allegations in their Opposition to suggest that they could plausibly assert a viable, parallel claim if permitted leave to do so. And Plaintiffs' claim that additional facts might be established through discovery, when such facts are not alleged or reasonably inferable from the pleadings, will not save Plaintiffs from judgment on the pleadings. *See, e.g., National Union Fire Ins. Co. v. Cargill, Inc.,* 61 F.4th 615, 619-20 (8th Cir. 2023) ("The absence of any such allegations here defeats National Union's request to proceed to discovery").

Plaintiffs' Opposition reveals the specific facts and allegations they would include in their Amended Complaint if permitted to do so. Namely, Plaintiffs will allege that Abiomed "failed to meet the F.D.A.'s requirements in its manufacturing of the product" as evidenced by six irrelevant "recalls" listed in their Opposition. *See* Doc. 34 at 3. Plaintiffs allege that those six recalls (only one of which even involve the same device, and none of which are relevant to Plaintiffs' allegations) show that the "product at issue" has been found, by the FDA, to "have a defect[] or flaw[] in the manufacturing process." *Id.* at 2.

In an attempt to retroactively plead allegations to support a manufacturing defect claim, Plaintiffs' Opposition references six irrelevant recalls.[5] However, only one of the six recalls even involves the device at issue (*i.e.*, Impella 5.5). *See* Ex. F. The others concern unrelated Abiomed products that Plaintiffs do not allege were ever inserted or otherwise in any way involved in Mrs. Urquhart's procedure or at issue in this case. *See* Ex. A–E (recall notices pertaining to the Impella 5.0 intravascular micro axial blood pump, Impella CP intravascular micro axial blood pump, Impella 2.5 intravascular micro axial blood pump, Impella CP with SmartAssist intravascular micro axial blood pump, and the Impella LD intravascular micro axial blood pump). In fact, none of the six recalls, including the one recall notice related to the Impella 5.5, even involve patients undergoing the same procedure as Mrs. Urquhart. According to the Complaint, Mrs. Urquhart was undergoing a mitral valve replacement procedure. Compl. at ¶ 9. The recall notice for the Impella 5.5, however, cautions physicians using the device in patients undergoing a transaortic valve replacement. Further, the recalls do not involve an improperly manufactured component, or call for the removal of a device from the field. *See* Ex. A–F.

Moreover, even if the one recall notice related to the Impella 5.5 actually involved the same procedure at issue in Mrs. Urquhart's case (which it does not as explained above), that recall related to the *design* of the device—not the *manufacturing* of the device. *See* Ex. F ("There is a potential for risk of unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impella blades."). This is further evidenced by the fact that the affected lots were not recalled for return from the field – rather, the recall referenced a forthcoming update to the device's Instructions for Use). *See*

5. For the Court's convenience, the recall notices referenced in Plaintiffs' Opposition are attached to this brief as Exhibits A–F.

Id. Thus, the only claim that could even potentially be alleged based on this "recall" is a design defect claim, and it is undisputed that a design defect claim is expressly preempted. *See e.g., Arthur v. Medtronic, Inc.,* No. 4:14-CV-52 CEJ, 2014 WL 3894365, at *6 (E.D. Mo. Aug. 11, 2014) (dismissing plaintiff's design defect claim, "[a]s most courts have found, a design defect claim is expressly preempted" by the MDA); *see also In re Medtronic, Inc.*, 623 F.3d at 1206 (noting design defect claims are *not* "parallel claims" and finding plaintiff's design defect claim expressly preempted).

Of course, even if Plaintiffs could present evidence that the Impella 5.5 had been subject to a relevant manufacturing defect-related recall (they cannot), a recall itself is not evidence that an actual defect existed in the at-issue product. *General Mills Ops., LLC v. Five Star Custom Foods, Ltd.*, 789 F. Supp. 2d 1149, 1155 (D. Minn. 2011) (despite there being "no dispute that a recall occurred," the plaintiff had "presented no evidence that the recalled meat was contaminated or defective in any way"). In short, nothing about Plaintiffs' newly presented "evidence" shows there was any manufacturing defect with the Impella 5.5 used to treat Mrs. Urquhart, nor does it suggest that any such defect caused her death.

Because any amendments to their Complaint, if permissible, would be futile, their request for leave to amend should be denied. Moreover, as discussed above, discovery is not required for this Court to grant Abiomed's Motion on the basis of preemption. Courts in this Circuit have granted motions for judgment on the pleadings and/or motions to dismiss on preemption grounds before discovery is had. *See In re Medtronic, Inc.*, 623 F.3d at 1207 (affirming dismissal of plaintiffs' inadequately pled manufacturing claims and noting plaintiffs were properly denied discovery to attempt to find a violation of federal requirements sufficient to state a claim); *see also Mattingly v. Medtronic, Inc.*, 486 F. Supp. 2d 964, 966 n.2 (E.D. Mo. 2007) (stating that the

question of preemption is a question of law, "thus factual discovery in this regard is of little or no consequence;" finding plaintiff's manufacturing, design, labeling, safety, and effectiveness claims all expressly preempted by the MDA). Despite publicly available federal requirements for the Impella 5.5, Plaintiffs do not even attempt to allege any manner in which the at-issue device deviated from these requirements in their Complaint (or in their Opposition). Plaintiffs should not be provided the opportunity to expand their inadequately pleaded claims by imposing the expense and burden of discovery on Abiomed. Instead, this Court should grant Abiomed's Motion for Judgment on the Pleadings, and enter judgment against Plaintiffs without permitting discovery.

CONCLUSION

For these reasons, Abiomed respectfully requests this Court grant its Rule 12(c) Motion for Judgment on the Pleadings as all claims brought against Abiomed by Plaintiffs Christopher Urquhart, individually, and as widower of Nancy June Urquhart, deceased, and Amy Ehlers, individually, and as daughter of Nancy June Urquhart, deceased, are preempted under federal law.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 13th day of January, 2025, a copy of the foregoing was sent by electronic mail using the CM/ECF system, which will send notification of such filing to:

Michael L. McGlynn
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ATTORNEYS FOR PLAINTIFFS

/s/ Bart C. Sullivan

EXHIBIT A

Class 1 Device Recall Impella 5.0

See Related Information[22]

Date Initiated by Firm	June 14, 2023
Date Posted	July 14, 2023
Recall Status[1]	Open[3], Classified
Recall Number	Z-2112-2023
Recall Event ID	92321[23]
Product Classification	Temporary non-roller type left heart support blood pump[24] - **Product Code** OZD[25]
Product	Impella 5.0 intravascular micro axial blood pump, Product Number 005062
Code Information	UDI-DI: 00813502011180;
Recalling Firm/ Manufacturer	Abiomed, Inc. 22 & 24 Cherry Hill Dr Danvers MA 01923-2575
For Additional Information Contact	Shashi Thoutam 734-262-6255
Manufacturer Reason for Recall	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.
FDA Determined Cause [2]	Under Investigation by firm
Action	An URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION) dated 6/14/23 was sent to customers. RECOMMENDATIONS: Clinicians are cautioned to position the Impella system carefully in patients with TAVR, and to be aware of this potential interaction. In this situation, clinicians should avoid repositioning while the device is spinning and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures. If there is low flow observed in a patient implanted with a TAVR while on Impella heart pump support, you should consider damage of the impeller and replace the Impella pump as soon as possible. ACTIONS TO BE TAKEN BY CUSTOMER/USER " Product is NOT being removed from the field and does not need to be returned. " Review, complete all fields, sign, and return the attached business response form (BRF) on the last page of this letter to the Recall Coordinator identified in this document.

	" Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products). " If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice. " Post a copy of this notice in a visible area for awareness of this field safety notice. " As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA s MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting- program/reporting-serious-problems-fda At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation. Th
Quantity in Commerce	9252 units
Distribution	Worldwide distribution - US Nationwide.
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=OZD

27. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

EXHIBIT B

Class 1 Device Recall Impella CP

See Related Information[22]

Date Initiated by Firm	June 14, 2023
Date Posted	July 14, 2023
Recall Status[1]	Open[3], Classified
Recall Number	Z-2115-2023
Recall Event ID	92321[23]
Product Classification	Temporary non-roller type left heart support blood pump[24] - **Product Code** OZD[25]
Product	Impella CP intravascular micro axial blood pump, Product Number 0048-0032
Code Information	UDI-DI: 00813502011388;
Recalling Firm/ Manufacturer	Abiomed, Inc. 22 & 24 Cherry Hill Dr Danvers MA 01923-2575
For Additional Information Contact	Shashi Thoutam 734-262-6255
Manufacturer Reason for Recall	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.
FDA Determined Cause [2]	Under Investigation by firm
Action	An URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION) dated 6/14/23 was sent to customers. RECOMMENDATIONS: Clinicians are cautioned to position the Impella system carefully in patients with TAVR, and to be aware of this potential interaction. In this situation, clinicians should avoid repositioning while the device is spinning and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures. If there is low flow observed in a patient implanted with a TAVR while on Impella heart pump support, you should consider damage of the impeller and replace the Impella pump as soon as possible. ACTIONS TO BE TAKEN BY CUSTOMER/USER " Product is NOT being removed from the field and does not need to be returned. " Review, complete all fields, sign, and return the attached business response form (BRF) on the last page of this letter to the Recall Coordinator identified in this document.

	" Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products). " If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice. " Post a copy of this notice in a visible area for awareness of this field safety notice. " As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA s MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting- program/reporting-serious-problems-fda At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation. Th
Quantity in Commerce	9252 units
Distribution	Worldwide distribution - US Nationwide.
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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27. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

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27. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

EXHIBIT C

Class 1 Device Recall Impella 2.5

See Related Information[22]

Date Initiated by Firm	June 14, 2023
Date Posted	July 14, 2023
Recall Status[1]	Open[3], Classified
Recall Number	Z-2111-2023
Recall Event ID	92321[23]
Product Classification	Temporary non-roller type left heart support blood pump[24] - **Product Code** OZD[25]
Product	Impella 2.5 intravascular micro axial blood pump, Product Number 005042
Code Information	UDI-DI: 00813502011081;
Recalling Firm/ Manufacturer	Abiomed, Inc. 22 & 24 Cherry Hill Dr Danvers MA 01923-2575
For Additional Information Contact	Shashi Thoutam 734-262-6255
Manufacturer Reason for Recall	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.
FDA Determined Cause [2]	Under Investigation by firm
Action	An URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION) dated 6/14/23 was sent to customers. RECOMMENDATIONS: Clinicians are cautioned to position the Impella system carefully in patients with TAVR, and to be aware of this potential interaction. In this situation, clinicians should avoid repositioning while the device is spinning and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures. If there is low flow observed in a patient implanted with a TAVR while on Impella heart pump support, you should consider damage of the impeller and replace the Impella pump as soon as possible. ACTIONS TO BE TAKEN BY CUSTOMER/USER " Product is NOT being removed from the field and does not need to be returned. " Review, complete all fields, sign, and return the attached business response form (BRF) on the last page of this letter to the Recall Coordinator identified in this document.

	" Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products). " If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice. " Post a copy of this notice in a visible area for awareness of this field safety notice. " As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA s MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting- program/reporting-serious-problems-fda At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation. Th
Quantity in Commerce	9252 units
Distribution	Worldwide distribution - US Nationwide.
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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27. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

EXHIBIT D

Class 1 Device Recall Impella CP with SmartAssist

Class 1 Device Recall Impella CP with SmartAssist

See Related Information[22]

Date Initiated by Firm	June 14, 2023
Date Posted	July 14, 2023
Recall Status[1]	Open[3], Classified
Recall Number	Z-2116-2023
Recall Event ID	92321[23]
Product Classification	Temporary non-roller type left heart support blood pump[24] - **Product Code** OZD[25]
Product	Impella CP with SmartAssist intravascular micro axial blood pump, Product Numbers 0048-0024, 0048-0045, 1000080
Code Information	UDI-DI: 00813502011371, 00813502011876, 00813502012279;
Recalling Firm/ Manufacturer	Abiomed, Inc. 22 & 24 Cherry Hill Dr Danvers MA 01923-2575
For Additional Information Contact	Shashi Thoutam 734-262-6255
Manufacturer Reason for Recall	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.
FDA Determined Cause [2]	Under Investigation by firm
Action	An URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION) dated 6/14/23 was sent to customers. RECOMMENDATIONS: Clinicians are cautioned to position the Impella system carefully in patients with TAVR, and to be aware of this potential interaction. In this situation, clinicians should avoid repositioning while the device is spinning and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures. If there is low flow observed in a patient implanted with a TAVR while on Impella heart pump support, you should consider damage of the impeller and replace the Impella pump as soon as possible. ACTIONS TO BE TAKEN BY CUSTOMER/USER " Product is NOT being removed from the field and does not need to be returned. " Review, complete all fields, sign, and return the attached business response form (BRF) on the last page of this letter to the Recall Coordinator identified in this

	document. " Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products). " If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice. " Post a copy of this notice in a visible area for awareness of this field safety notice. " As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA s MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting- program/reporting-serious-problems-fda At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation. Th
Quantity in Commerce	9252 units
Distribution	Worldwide distribution - US Nationwide.
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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27. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

EXHIBIT E

Class 1 Device Recall Impella LD

See Related Information[22]

Date Initiated by Firm	June 14, 2023
Date Posted	July 14, 2023
Recall Status[1]	Open[3], Classified
Recall Number	Z-2113-2023
Recall Event ID	92321[23]
Product Classification	Temporary non-roller type left heart support blood pump[24] - **Product Code** OZD[25]
Product	Impella LD intravascular micro axial blood pump, Product Number 005082
Code Information	UDI-DI: 00813502011227;
Recalling Firm/ Manufacturer	Abiomed, Inc. 22 & 24 Cherry Hill Dr Danvers MA 01923-2575
For Additional Information Contact	Shashi Thoutam 734-262-6255
Manufacturer Reason for Recall	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.
FDA Determined Cause [2]	Under Investigation by firm
Action	An URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION) dated 6/14/23 was sent to customers. RECOMMENDATIONS: Clinicians are cautioned to position the Impella system carefully in patients with TAVR, and to be aware of this potential interaction. In this situation, clinicians should avoid repositioning while the device is spinning and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures. If there is low flow observed in a patient implanted with a TAVR while on Impella heart pump support, you should consider damage of the impeller and replace the Impella pump as soon as possible. ACTIONS TO BE TAKEN BY CUSTOMER/USER " Product is NOT being removed from the field and does not need to be returned. " Review, complete all fields, sign, and return the attached business response form (BRF) on the last page of this letter to the Recall Coordinator identified in this document.

	" Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products). " If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice. " Post a copy of this notice in a visible area for awareness of this field safety notice. " As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA s MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting- program/reporting-serious-problems-fda At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation. Th
Quantity in Commerce	9252 units
Distribution	Worldwide distribution - US Nationwide.
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[27].

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EXHIBIT F

Class 1 Device Recall Impella 5.5 with SmartAssist

Class 1 Device Recall Impella 5.5 with SmartAssist

See Related Information[22]

Date Initiated by Firm	June 14, 2023
Date Posted	July 14, 2023
Recall Status[1]	Open[3], Classified
Recall Number	Z-2114-2023
Recall Event ID	92321[23]
Product Classification	Temporary non-roller type left heart support blood pump[24] - **Product Code** OZD[25]
Product	Impella 5.5 with SmartAssist intravascular micro axial blood pump, Product Numbers 0550-0008 and 1000100
Code Information	UDI-DI: 00813502011531, 00813502012828;
Recalling Firm/ Manufacturer	Abiomed, Inc. 22 & 24 Cherry Hill Dr Danvers MA 01923-2575
For Additional Information Contact	Shashi Thoutam 734-262-6255
Manufacturer Reason for Recall	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.
FDA Determined Cause [2]	Under Investigation by firm
Action	An URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION) dated 6/14/23 was sent to customers. RECOMMENDATIONS: Clinicians are cautioned to position the Impella system carefully in patients with TAVR, and to be aware of this potential interaction. In this situation, clinicians should avoid repositioning while the device is spinning and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures. If there is low flow observed in a patient implanted with a TAVR while on Impella heart pump support, you should consider damage of the impeller and replace the Impella pump as soon as possible. ACTIONS TO BE TAKEN BY CUSTOMER/USER " Product is NOT being removed from the field and does not need to be returned. " Review, complete all fields, sign, and return the attached business response form (BRF) on the last page of this letter to the Recall Coordinator identified in this

	document. " Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products). " If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice. " Post a copy of this notice in a visible area for awareness of this field safety notice. " As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA s MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting- program/reporting-serious-problems-fda At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation. Th
Quantity in Commerce	9252 units
Distribution	Worldwide distribution - US Nationwide.
Total Product Life Cycle	TPLC Device Report[26]

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