SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEPARTMENT 304

KATHERINE GALDAMEZ and MIRIAM ALSUGIRE,

Plaintiffs,

v.

ABBOTT CARDIOVASCULAR SYSTEMS, INC; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC., STANFORD HEALTH CARE, DIPANJAN BANERJEE, M.D., nominal defendants OMAR ALSUGIRE, ALI ALSUGIRE, and DOES 1-100, inclusive,

Defendants.

Case No. CGC-21-591082

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY ADJUDICATION

Defendants Abbott Cardiovascular Systems Inc., Thoratec LLC, and Thoratec Corporation's motion for summary adjudication came on for hearing on May 6, 2026. Having considered the pleadings and papers on file in the action, and the arguments of counsel presented at the hearing, the motion is hereby granted.

BACKGROUND

On November 17, 2021, Plaintiffs Katherine Galdamez and Miriam Alsugire ("Plaintiffs") filed this action against numerous defendants, including Defendants Abbott Cardiovascular Systems, Inc.,

Thoratec LLC, and Thoratec Corporation (collectively, "Abbott").[1] On November 21, 2025, Plaintiffs filed the operative Second Amended Complaint ("SAC"). Plaintiffs allege as follows:

Plaintiffs are the daughters and survivors of Doris Rodezno (also referred to as "Decedent"). (SAC ¶ 46.) Ms. Rodezno had installed a medical device, the HeartMate 3, designed and manufactured by Abbott. (*Id.* ¶¶ 4, 24, 30.) She was implanted with the device on March 23, 2016 at Stanford Health Care as part of a clinical trial. (*Id.* ¶¶ 24, 30.) During admission for installation of the device, she was provided direct contact information to Stanford Health Care by way of a telephone number to call in the event of a malfunction. (*Id.*) Decedent was promised that the emergency number provided to her was staffed 24/7 with persons knowledgeable about the HeartMate 3. (*Id.*)

On April 19, 2019, Ms. Rodezno was alerted to a malfunction in the HeartMate 3 by an alarm. (*Id.* ¶ 30.) The device's controllers prompted her to "Call Hospital Contact." (*Id.*) "The Heartmate 3 apparently had stopped pumping." (*Id.*) However, the emergency number Decedent was given was incorrect, and Stanford Health Care did not connect her to a HeartMate 3 trained provider, but to an advice nurse service untrained in the operation and repair of that device. (*Id.* ¶¶ 33-34.) Plaintiffs allege that Abbott breached a number of duties of care it purportedly owed Decedent, including a duty to provide her a correct emergency telephone number to call in the event of a malfunction and a duty of care in the design and manufacture of the device, and that those breaches were substantial factors in her death on the same date. (*Id.* ¶¶ 25-27, 39-43.)

Plaintiffs allege eight causes of action against Abbott: (1) negligence (wrongful death); (2) negligence (survival); (3) strict products liability (wrongful death); (4) strict products liability (wrongful death); (5) breach of warranty (wrongful death); (6) breach of warranty (survival); (7) failure to warn FDA and failure to recall; and (8) negligent misrepresentation. (*Id.* ¶¶ 1–258.) Abbott now seeks summary adjudication as to certain of those claims. Plaintiffs oppose the motion.

DEFENDANTS' REQUEST FOR JUDICIAL NOTICE

Abbott's Request for Judicial Notice ("RJN") of the FDA's IDE and PMA approval letters and related documents concerning the HeartMate 3 (RJN Exs. 1-6) is granted pursuant to Evidence Code

[1] Omar Alsugire and Ali Alsugire are named as nominal Defendants. (SAC ¶ 47.)

section 452(c).[2] (See, e.g., *Martinez v. Cot'n Wash, Inc.* (2022) 81 Cal.App.5th 1026, 1050 fn. 7 ["courts may take judicial notice of information published on official government websites" (cleaned up)]; *Eidson v. Medtronic, Inc.* (N.D. Cal. 2013) 981 F.Supp.2d 868, 878-879 [taking judicial notice of FDA PMA approval letter, database listings and other documents; "because all of the documents at issue appear on the FDA's public website, they may be judicially noticed"]; see also *EVO Brands, LLC v. Al Khalifa Group LLC* (C.D. Cal. 2023) 657 F.Supp.3d 1312, 1321-1322 [taking judicial notice of printout of webpage on FDA website, and observing that "[c]ourts have taken judicial notice of internet archives in the past, including Archive.org's 'Wayback Machine,' finding that Archive.org possesses sufficient indicia of accuracy that it can be used to readily determine the various historical versions of a website"].) Plaintiffs do not dispute the authenticity of these documents or that the FDA took the actions they reflect. (See, e.g., SAC ¶¶ 28 [June 19, 2014 application for Investigational Device Exemption to begin clinical trials for the Heartmate 3]; 29 [July 24, 2014 conditional approval of IDE application]; 31 [August 23, 2017 grant of premarket approval].)[3]

KEY UNDISPUTED BACKGROUND FACTS

The HeartMate 3 is a left ventricular assist system ("LVAS") medical device. (UMF 1; RJN Exs. 1-3.)[4] It is "used in patients with end-stage failure, when the natural heart is unable to maintain normal blood flows and/or pressure so that it cannot adequately provide oxygenated blood to the vital organs. It is intended to provide short-term support to the heart (for example, to help the patient's own heart to

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[2] Abbott's request for judicial notice of Exhibits 7 and 8, which concern the HeartMate II and the original HeartMate, is denied as irrelevant to the issues before the Court. (*Mangini v. R.J. Reynolds Tobacco Co.* (1994) 7 Cal.4th 1057, 1063 ["Although a court may judicially notice a variety of matters, only *relevant* material may be noticed" (cleaned up)], overruled on other grounds by *In re Tobacco Cases II* (2007) 41 Cal.4th 1257.)

[3] Indeed, Plaintiffs include several of the same documents in their opposition papers. (See Righthand Decl. Exs. K, L, M, T.)

[4] "UMF" refers to Abbott's Separate Statement of Facts. In many cases, Plaintiffs fail to state unequivocally whether each fact in Defendants' separate statement is disputed or undisputed, as required. (Code Civ. Proc. § 437c(b)(3); Cal. Rules of Court, rule 3.1350(f).) Instead, they litter the record with meritless "objections," deny asserted facts that are not genuinely in dispute, provide evasive and argumentative responses, and allege additional facts that do not actually contradict the asserted fact. There is no genuine dispute as to any of the facts cited here. (See *Beltran v. Hard Rock Licensing, Inc.* (2023) 97 Cal.App.5th 865, 875-876 [courts should "not hesitate to disregard attempts to game the system by the opposing party claiming facts are 'disputed' when the uncontroverted evidence clearly shows otherwise"].)

recover or to support the patient until heart transplantation)." (RJN Ex. 4.) It is composed of an implanted centrifugal blood pump which helps the left ventricle (the main pumping chamber of the heart) pump blood to the rest of the body, as well as other components including a driveline (percutaneous cable) that connects to an external system controller, which is powered by a power module (for hospital use), a mobile power unit that connects to AC power, or by two batteries that the patient carries. (RJN Ex. 3, 1-2; RJN Ex. 4.)

In 2014, Abbott obtained investigational drug exemption ("IDE") approval from the FDA for a clinical trial (the "Momentum 3" clinical trial) of the HeartMate 3, an experimental device. (UMF 2; RJN Ex. 3, 13-39; RJN Ex. 6.) On July 24, 2014, the FDA initially granted conditional approval, and on October 15, 2014, noting that Abbott had corrected deficiencies found in that conditional approval letter, it granted Abbott's application without condition. (RJN Ex. 6.)[5] Decedent received the HeartMate 3 in March 2016 as part of her voluntary participation in that clinical trial, which was conducted at approximately 69 hospitals in the United States, including Stanford Health Care. (UMF 18; Holder Decl. Ex. 9, 6.) The Clinical Trial Agreement between Abbott and Stanford Health Care stated that "[Stanford] is an independent contractor to [Abbott Defendants], and not a partner, agent, employee, representative or joint-venture of [Abbott Defendants]." (UMF 62; Righthand Decl., Ex. N § 14.8.) It further provided that the Agreement "sets forth the entire understanding among the Parties about the Study," and that "[a]ny modification or waiver to this Agreement must be in writing and signed by all parties to this Agreement." (Righthand Decl. Ex. N § 143.)

On August 23, 2017, the FDA granted Abbott's premarket approval application ("PMA") for the HeartMate 3 for short-term hemodynamic support (e.g., as a bridge to transplant or myocardial recovery) in patients with advanced refractory left ventricular heart failure. (UMF 4; RJN Exs. 1-3.) It specified that the manufacturer must obtain FDA approval before making any change affecting the safety or effectiveness of the device. (*Id.*; RJN Ex. 2, 2.) The FDA has continued to grant Premarket Approvals for the HeartMate 3 since then. (UMF 4; RJN Ex. 5.)[6]

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[5] Plaintiffs' contention that when Decedent received her implant on March 23, 2016, "the FDA had approved the IDE conditionally only" (Opposition, 2) is inaccurate.

[6] Plaintiffs filed their voluminous supporting documents and evidence conditionally under seal. By separate order, the Court grants Abbott's unopposed motion to file under seal certain of the exhibits to

LEGAL STANDARD

"A party may move for summary adjudication as to one or more causes of action within an action, . . . 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, . . . 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 motion for summary adjudication shall be granted only if it completely disposes of a cause of action, an affirmative defense, a claim for damages, or an issue of duty." (*Id.*) "There is a triable issue of material fact if, and only if, the evidence would allow a reasonable trier of fact to find the underlying fact in favor of the party opposing the motion in accordance with the applicable standard of proof." (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 850.)

While a summary adjudication motion must completely dispose of a cause of action (Code Civ. Proc. § 437c(f)(1)), the manner in which a "cause of action" is pled in the complaint is not dispositive. (*Lilienthal & Fowler v. Superior Court* (1993) 12 Cal.App.4th 1848, 1854 [summary adjudication proper as to "two separate and distinct causes of action regardless of how pled in the complaint"].) Rather, "[a] recognized exception to the statutory language above holds that where two or more separate and distinct wrongful acts are combined in the same cause of action in a complaint, a party may present a summary adjudication motion that pertains to some, but not all, of the separate and distinct wrongful acts." (*Blue Mountain Enterprises, LLC v. Owen* (2022) 74 Cal.App.5th 537, 549 [trial court properly resolved claim for breach of contract by summary adjudication where complaint alleged separate and distinct violations of different provisions of employment agreement]; accord, *CDF Firefighters v. Maldonado* (2011) 200 Cal.App.4th 158, 165 [despite being pled as one cause of action in the complaint, plaintiff stated two causes of action]; *Lilienthal & Fowler*, 12 Cal.App.4th at 1854-1855 [under section 437c(f), "a party may present a motion for summary adjudication challenging separate and distinct wrongful act even though combined with other wrongful acts alleged in the same cause of action."].) The statute thus authorizes motions for summary adjudication that "reduce the costs and length" of litigation by limiting the

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Plaintiffs' opposition.

substantive areas of dispute. (*Lilienthal & Fowler*, 12 Cal.App.4th at 1852.)[7]

"Federal preemption presents a question of law." (*Amiodarone Cases* (2022) 84 Cal.App.5th 1091, 1101; accord, *Glennen v. Allergan, Inc.* (2016) 247 Cal.App.4th 1, 6 ["federal preemption presents a pure question of law" (cleaned up)].)

DISCUSSION

I. Plaintiffs' Design Defect, Failure To Recall, And Implied Warranty Claims Are Preempted By Federal Law.

Abbott contends first that Plaintiffs' design defect, failure to recall, and implied warranty claims are preempted by federal law because the HeartMate 3 received both IDE and PMA from the FDA. (Opening Brief, 5-10.) Plaintiffs raise several arguments in opposition, arguing (1) that there is no pre-approval preemption for design claims (Opposition, 9-10); (2) that Plaintiffs' claims are "parallel" claims that are not preempted (*id.* at 11-13); and (3) that Plaintiffs' design defect claim is not preempted by the FDA's IDE approval (*id.* at 13-14). Plaintiffs also argue that their failure to recall and warn cause of action is not preempted. (*Id.* at 16-18.)

A. Background Law

Federal law preempts conflicting state law. (U.S. Const., art. VI, cl. 2.) Preemption may be express or implied. "The term express preemption refers to Congress's use of express language in a statute to supersede state law. Whether Congress has expressly preempted a state law claim is primarily a question of statutory construction." (*Quishenberry v. UnitedHealthcare, Inc.* (2023) 14 Cal.5th 1057, 1064-1065 (cleaned up).) "Implied preemption occurs: (1) when state law regulates conduct in a field that Congress intended the Federal Government to occupy exclusively, or (2) where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (*Glennen*, 247 Cal.App.4th at 9 (cleaned up).)

1. Express Preemption

The Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act

[7] For this reason, Plaintiffs' apparent contention that summary adjudication should be denied because Abbott's motion fails to dispose of an entire cause of action (e.g., Opposition, 3, 9) lacks merit.

("FDCA") created a "regime of detailed federal oversight" for medical devices. (*Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 316.) The MDA establishes, in order of increasing regulatory scrutiny, three classes of medical devices: Class I, Class II, and Class III. (*Id.* at 317.) "A class III device," such as the HeartMate 3,[8] "receives the most federal oversight, and requires premarket approval by the FDA." (*McGuan v. Endovascular Technologies, Inc.* (2010) 182 Cal.App.4th 974, 977 (cleaned up).) "However, prior to obtaining premarket approval, a manufacturer of a class III device may apply for Food and Drug Administration (FDA) authorization to use the device for clinical testing pursuant to an investigational device exemption (IDE)." (*Robinson v. Endovascular Technologies, Inc.* (2010) 190 Cal.App.4th 1490, 1493.) In order to obtain an IDE, an applicant must submit extensive information, including

> a plan for any proposed clinical testing of the device and a report of prior investigations of the device; information about the methods, facilities and controls used for the manufacture, processing, packing, storage and installation of the device; an example of agreements to be executed by all investigators and the identities of all such investigators; details of each [institutional review board] that has been or will be asked to review the investigation and certification of the IRB's decision; details about the institution where the testing will occur; proposed labeling for the device; and copies of all forms and institutional materials to be provided to subjects to obtain informed consent.

(*Id.*) After reviewing this information, the FDA notifies the applicant that the proposed investigation has been approved, approved with modifications, or disapproved. (*Id.*) "After the IDE application has been approved, the FDA prohibits any deviation from the investigational plan, design, manufacturing techniques, clinical protocol, warnings or consent form which could potentially affect clinical subjects unless the FDA first approves the change." (*Id.* at 1494.) "The FDA may withdraw its approval at any time in the event that an applicant does not comply with the approved clinical protocol." (*Id.*)

The MDA contains an express preemption clause that states:

> Except as provided in subdivision (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter

[8] It is undisputed that the HeartMate 3 is a Class III device.

included in a requirement applicable to the device under this chapter.

(21 U.S.C. § 360k(a).)[9]

In *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, the United States Supreme Court established a two-part test for express preemption under the MDA: (1) whether the Federal Government has established requirements applicable to the specific device; and (2) whether the state law claim imposes requirements with respect to the device that are "different from, or in addition to," the federal ones, and that relate to safety and effectiveness. (552 U.S. at 321.) As to the first prong of the test, the Court held that premarket approval by the FDA imposes "requirements" under the MDA. (*Id.* at 322-323.) Unlike the separate Section 510(k) clearance process for devices that are "substantially equivalent" to devices that were already on the market before the enactment of the MDA, and hence are exempt from premarket approval, it is "focused on safety, not equivalence." (*Id.* at 317, 323.) As to the second part of the test, the Court held that "references to a State's 'requirements' includes its common-law duties." (*Id.* at 324.) It concluded 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." (*Id.* at 323-324.)

The Court in *Riegel* recognized an exception to this rule of express preemption: "[Section] 360k 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.) This "parallel claim" exception to federal preemption is a narrow one, and requires a plaintiff seeking to invoke it to show both (1) an alleged violation of specific FDA regulations or requirements related to the device and (2) a causal nexus between the alleged violation and the plaintiff's injury. (E.g., *Weber v. Allergan, Inc.* (9th Cir. 2019) 940 F.3d 1106, 1112 ["for a state law claim to survive express preemption under the MDA, a plaintiff must show that the defendant deviated from a particular pre-market approval or other FDA requirement applicable to the Class III medical device"]; *Eidson*, 981 F.Supp.2d at 880; *Houston v. Medtronic, Inc.* (C.D. Cal. 2013) 957 F.Supp.2d 1166, 1174.)

Plaintiffs argue that to meet its burden on summary adjudication to show preemption, "Abbott must demonstrate that it was impossible for it to comply with both state and federal requirements."

[9] Subdivision (b) of the statute is inapplicable here.

(Opposition, 9; see also *id.* at 9-10 and authorities cited in note 5.) Not so. "Impossibility preemption" refers to one type of implied preemption (also referred to as "conflict preemption"), and has nothing to do with express preemption. (See *Pilliod v. Monsanto Co.* (2021) 67 Cal.App.5th 591, 613.) As Abbott correctly points out (Reply, 2-4), this aspect of implied preemption, which stems from *Wyeth v. Levine* (2009) 555 U.S. 555, has been applied in cases relating to prescription drugs, not those relating to medical devices, because Congress did not extend the express preemption provision in § 360k to prescription drugs. (*Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.* (9th Cir. 2022) 48 F.4th 1040, 1046 ["*Wyeth v. Levine* addressed preemption in the context of prescription drugs, not medical devices, so . . . no applicable express preemption clause applied" (cleaned up)]; *In re Medtronic, Inc., Sprint-Fidelis Leads Products Liability Litigation* (8th Cir. 2010) 623 F.3d 1200, 1205 ["*Wyeth* turned on implied conflict preemption, not express preemption, because Congress did not extend the express preemption for medical devices in § 360k to prescription drugs."].)

2. Implied Preemption

"Even if a plaintiff's claim is not expressly preempted, it will be deemed impliedly preempted if it conflicts with the FDCA's enforcement scheme." (*Glennen*, 247 Cal.App.4th at 10.) "Implied preemption under the MDA bars claims seeking to enforce an exclusively federal requirement that is not grounded in traditional state tort law." (*Id.*) It also bars claims that would conflict with the FDA's responsibility and authority to oversee compliance with the "detailed regulatory regime" under the FDCA. (*Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 349-350 [holding that state-law "fraud-on-the-FDA claims were preempted because they would "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA]'s judgment and objectives"]; see also *McGuan*, 182 Cal.App.4th at 983-986 [state law claim for fraudulent concealment impliedly preempted].)

"Together, express preemption and implied preemption identify a narrow gap through which a state-law claim must fit to escape preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." (*Glennen*, 247 Cal.App.4th at 11-12 (cleaned up).) Thus, "in order to survive preemption, such claims must be

premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." (*Id.* at 12 (cleaned up).)

B. Analysis

The Court agrees with Abbott's contention that Plaintiffs' design defect, implied warranty, and failure to recall claims are expressly preempted. None of those claims are "parallel" claims that fall within the narrow exception to the two-part *Riegel* test. The Court therefore concludes they are preempted by the MDA.[10]

1. Under Controlling Authority, The IDE Has Preemptive Effect.

The first prong of the *Riegel* test—whether the FDA has established requirements for the subject device—is clearly met as to all of Plaintiffs' claims. In *Riegel*, the Supreme Court held that § 360k(a) expressly preempted common-law claims for negligence, strict liability, and breach of implied warranty challenging the safety and effectiveness of a Class III device (a cardiac balloon catheter) that had received premarket approval from the FDA. The Court determined that "[p]remarket approval . . . imposes 'requirements' under the MDA." (552 U.S. at 322.) "Unlike general label duties, premarket approval is specific to individual devices." (*Id.* at 322-323.) The same conclusion applies here to Plaintiffs' claims, which similarly challenge the safety and effectiveness of the HeartMate 3, a Class III device.

Plaintiffs argue that because Decedent's HeartMate 3 was designed prior to the FDA's decision to grant premarket approval, although it was implanted after the FDA granted Abbott's IDE application, their design defect claims are not preempted. (Opposition, 9-14.)[11] However, binding California authority is to the contrary. *Robinson v. Endovascular Technologies, Inc.* (2010) 190 Cal.App.4th 1490 involved claims against the manufacturer of a class III medical device, an implanted bifurcated graft. As in this case, defendants' application for an IDE to conduct clinical trials for the device was granted, and

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[10] The Court's decision is consistent with an "extensive body of decisional law" in the Ninth Circuit since *Riegel*, in which "[t]he overwhelming majority of state law tort claims, including claims based on negligence, design defect, manufacturing defect, failure to warn, fraud, negligent misrepresentation, breach of implied and express warranties, unfair competition, and false advertising, have been held preempted." (*De La Paz v. Bayer Healthcare LLC* (N.D. Cal. 2016) 159 F.Supp.3d 1085, 1092 [collecting authorities].)

[11] Although Plaintiffs raise the argument solely in connection with their design defect claims, the same analysis applies to their other claims.

the plaintiff agreed to participate in the IDE clinical study for the device. (*Id.* at 1494-1495.) The consent form stated that the study was designed to "determine the long term safety and effectiveness of a new investigational device," and disclosed potential risks. (*Id.* at 1495.)[12] Plaintiff was then implanted with the device. (*Id.*) The following year, defendants submitted a premarket approval application, which the FDA granted. (*Id.*) Plaintiff alleged he had suffered severe personal injuries after he was implanted with the device, and brought causes of action for strict product liability, negligence, breach of warranty, fraudulent concealment, and punitive damages, including claims for "defects in the design, testing, and manufacture" of the device. (*Id.* at 1498.) Defendants moved for summary judgment on the ground that plaintiff's claims were preempted by section 360(k) of the MDA. The trial court granted the motion, and the Court of Appeal affirmed.

The court noted that in its prior decision in *McGuan*, it had held that "state law claims for strict product liability, negligence, breach of express warranty, and breach of implied warranty" in connection with the same device were preempted by the MDA. (*Id.* at 1498.) It acknowledged that in contrast to *McGuan* and *Riegel*, "the present case does not involve premarket approval" of the device. (*Id.*) Plaintiff argued that "under *Riegel* state claims are preempted only after an FDA finding of safety and effectiveness" in a PMA, and that an IDE approval is analogous to the § 510(k) approval involved in *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, in which the Court held that the plaintiff's state law claims involving a medical device that had received § 510(k) approval were not preempted. (*Id.*) The court rejected that argument, concluding that "IDE approval of a medical device is more similar to premarket approval than § 510(k) approval." (*Id.* at 1499.) The court explained,

> Although the IDE process and the PMA process are not identical, a comparison of the governing regulations reveals no material differences. In granting IDE approval, the FDA imposes detailed requirements on the design, manufacture, and warnings for class III devices as well as the conduct of the clinical investigation. Prior to granting IDE approval, the FDA must determine whether "the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or there is reason to believe that the device as used is ineffective." Thus, these requirements allow the FDA to evaluate the safety and effectiveness of the device.

[12] Plaintiffs' decedent executed a similar consent form. (Righthand Decl. Ex. I.) The potential risks of the clinical trial it disclosed included substantial risks at 6 and 12 months following implantation of the device of death, cardiac arrhythmia, heart failure, and other conditions. (*Id.* at 9-10.)

(*Id.* (cleaned up); see also *Martin v. Telectronics Pacing Systems, Inc.* (6th Cir. 1997) 105 F.3d 1090, 1095-1096 [summarizing IDE requirements]; 21 C.F.R. §§ 812.20, 812.25.) "Safety and effectiveness of the device, however, are not paramount concerns in § 510(k) approval." (*Id.*) The court disagreed that an FDA finding that a medical device is safe and effective is necessary for IDE preemption, agreeing that "[t]he FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental." (*Id.*, quoting *Slater v. Optical Radiation Corp.* (7th Cir. 1992) 961 F.2d 1330, 1333 [in case of first impression, holding that an IDE preempts state law products liability claims, including claims for design defects, relating to the safety or effectiveness of the device].)[13] Accordingly, the court expressly held that "*Riegel* is controlling in cases involving medical devices that have received IDE approval." (*Id.* at 1500.)

Plaintiffs attempt to avoid *Robinson*, arguing that it is "a 15-year-old case" and "stands alone in its conclusion." (Opposition, 13.)[14] Their argument is unavailing: *Robinson*, which has never been questioned or limited, is controlling authority that this Court is bound to follow. (*Auto Equity Sales, Inc. v. Superior Court* (1962) 57 Cal.2d 450, 455.)[15]

2. Design Defect (Negligence and Strict Products Liability)

In their First and Second Causes of Action for negligence, Plaintiffs allege that Defendants breached their duty of care by defectively designing the product and submitting it for IDE approval. (SAC ¶¶ 34-40, 82-85.) Likewise, in the Third and Fourth Causes of Action, Plaintiffs seek to state claims for strict products liability, alleging that the HeartMate 3 "did not perform as safely as an ordinary consumer would have expected it to perform when used or misused in an intended or reasonably foreseeable way," and that its defective design was a substantial factor in causing Decedent's death.

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[13] Accord, *Martin*, 105 F.3d at 1099 ["To allow a cause of action for design defect where the FDA has specifically approved of the design of the device for investigational purposes would thwart the goals of safety and innovation"].)

[14] *Robinson* does ***not*** "stand alone": as noted above, at least two federal circuits agree with its holding.

[15] Plaintiffs contend that "Abbott had a duty under state law to create a safe design that it could have satisfied without coming into conflict with any federal requirement." (Opposition, 9-10.) However, the federal cases they rely upon are inapposite. *Kaiser v. Johnson & Johnson* (7th Cir. 2020) 947 F.3d 996 involved FDA clearance under the § 510(k) regulatory scheme, which as discussed in text is governed by the Supreme Court's holding in *Medtronic*, not by *Riegel*. (See 947 F.3d at 1008-1009.) The other cases Plaintiffs cite involved application of the impossibility standard to prescription drugs. (*Holley v. Gilead Sciences, Inc.* (N.D. Cal. 2019) 379 F.Supp.3d 809, 818-821; *In re: Tepezza Marketing, Sales Practices, and Products Liability Litigation* (N.D. Ill. Nov. 3, 2023) 2023 WL 7281665, *2.)

(SAC ¶¶ 120, 147.)[16] Plaintiffs contend that the device failed due to an incorrectly inserted driveline that was made possible by the alleged design defect. (Resp. to UMF 8.) In particular, they contend that "[t]he device had a classic product design defect. . . . The problem was and is that there were two ports on the Controller and the Driveline was capable of being inserted 180 degrees opposite its intended insertion point blowing a fuse and shorting the system." (Opposition, 5; see also Holder Decl. Ex. 11, 4-5 [the device was designed "with an electrical system that was reliant on fuse technology susceptible to failure without immediate remedy disabling the heart pump device, a driveline connection designed . . . in a way that it could be inadvertently inserted in a fashion that would short the device," and "designed in a way that the foreseeable user would need to exchange the controller at some point, however design allowed the user to insert the driveline backwards in to the HM3 controller, leading to a blown fuse . . . . The device should have been designed so that driveline insertion could exist in only one way with no other attempted insertion having impact on the device."].)

The design features that Plaintiffs complain about were expressly approved by the FDA when it granted the IDE. Plaintiffs' design defect claims therefore are preempted, whether they are couched as strict products liability or negligence claims. "Since the FDA authorized the use of the [device] for clinical testing pursuant to an IDE prior to plaintiff's surgery, the FDA approved the device's design . . . . Thus, to the extent that plaintiff's complaint alleged that the [device] was unsafe . . . , he was seeking to impose state law requirements that were 'different from, or in addition to,' the MDA. Consequently, the state law claims were preempted under the MDA." (*Robinson*, 190 Cal.App.4th at 1500; *McGuan*, 182 Cal.App.4th at 983 [affirming summary judgment, holding that state law claims for strict products liability for alleged design defects were preempted]; see also, e.g., *De La Paz,* 159 F.Supp.3d at 1092 ["*Every* design-defect claim considered within our circuit has been held preempted (such a claim would

[16] Plaintiffs refer indiscriminately in their opposition papers to their design defect and manufacturing defect claims. (See Opposition, 3 [referring to Health & Safety Code § 111635's requirement that manufacturers operate in compliance with federal Good Manufacturing Practices (GMP) regulations]; *id.* at 12 [citing Health & Safety Code §§ 111295 and 111260 and 21 C.F.R. § 820.70, relating to "adulterated" devices that are not manufactured in conformity with current good manufacturing practice].) However, Abbott has not moved for summary adjudication as to the latter category of claims. (See Motion, 2 [Summary Adjudication Issue 1]; Reply, 6-7 ["there is no manufacturing defect at issue in this motion for summary adjudication"].)

require allegations of deviations from the FDA-approved design)."].)[17]

3. Failure To Recall

Plaintiffs contend in the Seventh Cause of Action that Abbott had a duty to recall the HeartMate 3 due to its alleged defective design. (SAC ¶ 227 ["DEFENDANTS breached their duty under California law to comply with federal and state law to remove from market the HeartMate 3 when they were presented with sufficient evidence and notice of the same that it presented a risk of injury or death"]; *id.* ¶¶ 226, 228.) Abbott seeks summary adjudication of this claim on three grounds: that it is expressly preempted by the MDA, that it is impliedly preempted, and that California law does not recognize such a claim in any event. (Opening Brief, 9-10; Reply, 6.) Plaintiffs do not respond directly to Abbott's arguments or cited authority, and seemingly disclaim any intention to pursue their failure to recall theory. (See Opposition, 16 ["It is not that Abbott had to 'stop selling' the HM3"].) Instead, their Opposition addresses a different claim: that Abbott breached its duty to ***warn the FDA*** of the risks of the device and to report adverse events. (*Id.* at 16-18.) But that is a separate and distinct claim on which Abbott does not seek summary adjudication.[18] Plaintiffs having failed to respond to the motion, it must be granted. In any event, Abbott is entitled to summary adjudication of the failure to recall claim on its merits.

The claim is preempted. Once the FDA grants an application for an IDE, the FDA's regulations provide that it may withdraw approval of the application if it finds, among other grounds, that "[t]here is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the

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[17] As an alternative ground, Abbott asserts that strict liability-based design defect claims as to implanted medical devices are not permitted under California law. (Opening Brief, 11.) The Court agrees. (*Armstrong v. Optical Radiation Corp.* (1996) 50 Cal.App.4th 580, 595 ["California law precludes strict liability for a *design* defect in a medical device. In the context of medical devices, design defects must be pursued under a negligence theory."]; *Hufft v. Horowitz* (1992) 4 Cal.App.4th 8, 19-20 ["We hold that a manufacturer is not strictly liable for injuries caused by an implanted prescription medical product which has been (1) properly made and (2) distributed with information regarding risks and dangers of which the manufacturer knew or should have known at the time"].) Plaintiffs' attempt to distinguish this authority on the ground that the HeartMate 3 was "not properly made" (Opposition, 15) rests on their design defect claim, which as discussed above is preempted.

[18] See *Stengel v. Medtronic Inc.* (9th Cir. 2013) 704 F.3d 1224, 1233 [holding that MDA did not preempt state-law claim for failing to report known risks associated with use of medical device to the FDA].) To prevail on their failure to warn claim, Plaintiffs "will ultimately have to prove that if [Abbott] had properly reported the adverse events to the FDA as required under federal law, that information would have reached the [Decedent's] doctors in time to prevent [her] injuries." (*Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413, 429-430 (cleaned up).)

investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective." (21 C.F.R. § 812.30(b)(4).) Once it issues a PMA, similarly, the FDA has authority to order the recall of a medical device where it finds that "there is a reasonable probability that [the] device . . . would cause serious, adverse health consequences or death." (21 U.S.C. § 360h(e)(1); 21 C.F.R. § 810.10 *et seq.*) The FDA regulations also contemplate voluntary recall by manufacturers of products "that present a risk of injury or gross deception or are otherwise defective." (21 C.F.R. § 7.40.)

Allowing a plaintiff to bring a state-law claim against a manufacturer for failure to recall a device approved by the FDA would impermissibly allow private enforcement of the FDCA, a federal statute for which Congress has provided no private right of action. (See 21 U.S.C. § 337(a) ["All such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"]; *Buckman*, 531 U.S. at 349 n.4 ["The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"].) Moreover, it would interfere with the FDA's unique authority to recall devices it has approved for use in clinical trials and medical treatment. (See *Buckman*, 531 U.S. at 350-351 ["complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants," and "would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court."]; see also, e.g., *Bianco v. Baxter Healthcare Corp.* (2008) 158 Cal.App.4th 1039, 1055 [recognizing that "FDA regulations govern the recall process," and that claims in tension with the FDA's regulatory authority are preempted]; *Poozhikala v. Medtronic Inc.* (C.D. Cal. 2022) 2022 WL 6120276, *5 n.4 ["Plaintiffs cannot premise their claim on the lack of a recall"]; *National Women's Health Network, Inc. v. A. H. Robins Co., Inc.* (D. Mass. 1982) 545 F.Supp. 1177, 1178-1180 [dismissing private claims seeking notification and recall of the Dalkon Shield as inconsistent with the 1976 amendments to the FDCA, which expressly "vested the power to seek these remedies *in the Secretary*"].)

At the hearing, Plaintiffs clarified that their failure to warn/failure to recall claim is based on the contention that once Abbott was on notice that the device posed a risk of injuries or death, it had a duty either to warn the patients or physicians involved in the clinical trial or to swap out or retrofit the

controllers containing the alleged defect. (See Opposition, 16 ["With some immediacy all Abbott should have done was warn both those who already had the device and those who possessed the devices for sale once it knew about the problem in 2015 and early 2016 and swap out the Controllers and modular cables."]; see also Righthand Decl. Ex. N, 53:7-12 [deposition question defining "recall" as "the process of taking a component of a product off the market and switching it out with a new or redesigned component."]; *id.* at 55:14-20 [Abbott did not "go back to those individuals who already had the HeartMate 3 and attempt to switch out their old controllers and drivelines for the redesigned controllers and drivelines"]; *id.* at 56:19-57:9 [similar].) While that theory is not clearly articulated in the Second Amended Complaint, it would fail for the same reason: a state law tort claim that would require a manufacturer to give different warnings than those required by the FDA or to modify the design of a device whose design had already been approved by the FDA in an IDE would be preempted for the reasons discussed above. (See *Coleman*, 223 Cal.App.4th at 424 ["A state law claim that the FDA-approved warnings on a class III medical device are inadequate, or that a device manufacturer failed to give additional warnings regarding use of the device, would be expressly preempted because the claim would impose a requirement under state law that is different than or in addition to what is required under federal law."]; *Robinson*, 190 Cal.App.4th at 1500 ["Since the FDA authorized the use of the Ancure Device for clinical testing pursuant to an IDE prior to plaintiff's surgery, the FDA approved the device's design, testing, intended use, manufacturing methods, and labeling. Thus, to the extent that plaintiff's complaint alleged that the Ancure Device was unsafe and its warnings were inadequate, he was seeking to impose state law requirements that were 'different from, or in addition to" the MDA. Consequently, the state law claims were preempted under the MDA." (cleaned up)].)

4. Implied Warranty

Plaintiffs allege in the Fifth and Sixth Causes of Action that Abbott "implicitly warranted to [Decedent] that the HeartMate 3 and its components were safe to use because in the event of a malfunction," there would be an emergency number to call available 24/7 and staffed by persons knowledgeable about the device. (SAC ¶¶ 185-189, 202-206.) Abbott moves for summary adjudication of this claim on two grounds: (1) there is no privity between the parties, as required by California law; and

(2) the claim is preempted. (Opening Brief, 10.) Plaintiffs, again, fail to respond. The motion is granted on both grounds.

First, Plaintiffs' claim fails for lack of privity. "Privity of contract is a prerequisite in California for recovery on a theory of breach of implied warranties of fitness and merchantability." (*Blanco*, 158 Cal.App.4th at 582 (cleaned up) [implied warranty claim against heart valve manufacturer dismissed for lack of privity]; accord, *Evraets v. Intermedics Intraocular, Inc.* (1994) 29 Cal.App.4th 779, 788.) Here, it is undisputed that Ms. Rodezno received the HeartMate 3 from Stanford, not from Abbott. (UMF 30.)

Second, Plaintiffs' implied warranty claim is preempted. (See, e.g., *Riegel*, 552 U.S. at 327-330 [state-law claim for breach of implied warranty against manufacturer of medical device was preempted]; *Robinson*, 190 Cal.App.4th at 1499-1500 [IDE approval preempted plaintiff's implied warranty claims]; see also *De La Paz*, 159 F.Supp.3d at 1097-1098 ["[Plaintiff's] claim for breach of the implied warranty of merchantability is preempted. A determination of whether the . . . device is fit for ordinary use bears directly on its safety and effectiveness."].)[19]

II. Abbott Is Entitled To Summary Adjudication Of Plaintiffs' Claims Based On Stanford's Emergency Phone Number.

Plaintiffs' claims for negligence, express warranty, and negligent misrepresentation turn in substantial part on their repeated allegation that Ms. Rodezno was given an incorrect or inadequate emergency telephone number to call in the event of a malfunction in the HeartMate 3, resulting in failure of the device, which was a substantial factor in causing her death. (E.g., SAC ¶¶ 33-34, 41-42, 48.) Abbott seeks summary adjudication of these claims on the ground that "the overwhelming evidence confirms that the Abbott Defendants were not involved in or responsible for Stanford's Emergency Phone Number and were also not in a joint venture with Stanford and thus cannot be held accountable for Stanford's Emergency Phone Number." (Motion, 2-3 [Summary Adjudication Issues 5-7]; Opening Brief 12-17.) Plaintiffs oppose the motion, contending that whether Abbott and Stanford formed a joint venture presents a disputed issue of fact such that their warranty and misrepresentation claims survive summary

[19] Plaintiffs also raise an *express* warranty claim relating to the emergency telephone number. (SAC ¶¶ 179-184, 196-201.) Although Abbott does not move for summary adjudication of that separate claim on lack of privity or preemption grounds, it would also appear to fail for the same reasons as the implied warranty claim. Regardless, Abbott is entitled to summary adjudication of the express warranty claim for the reasons discussed in Part II, *infra*.

adjudication. (Opposition, 19-20.) The Court disagrees.

Plaintiffs do not genuinely dispute Abbott's showing that it had no involvement in or responsibility for Stanford's emergency phone number. Plaintiffs allege that Ms. Rodezno "was provided direct contact information *to STANFORD HEALTH CARE* by way of a telephone number to call in the event of a HeartMate 3 malfunction. . . ." (SAC ¶ 24 (emphasis added); see also Opposition, 19 [referring to "the incorrect emergency numbers provided to Decedent by Stanford"].) It is undisputed that Stanford, not Abbott, provided Ms. Rodezno with that emergency number; that it appeared in handouts she received at the time of the implant; and that Stanford, not Abbott, staffed the number with advice nurses, who in turn could contact the surgeon, who was the principal investigator for Stanford involved in the clinical trial. (E.g., Righthand Decl. Ex. EE [Stanford University Medical Center, VAD Phone List of office and page numbers for Stanford physicians, nurses, and patient care coordinator; "If there is an urgent or emergent issue, contact the Page Operator at **(650) 723-6661**."];[20] see also Holder Decl. Ex. 9, 25 ["For support with her HeartMate 3, including any alarms, plaintiffs' decedent was instructed to promptly call (650) 723-6661, and to ask for the VAD Team Pager #12502. . . . Plaintiffs' decedent received numerous handouts with the VAD 24-hour/day phone number"]; *id.* Ex. 10, 13 ["[Abbott] . . . did not provide Ms. Rodezno with a telephone number to call in case of an emergency related to her HM3"].) Thus, even if, as Plaintiffs contend, Stanford negligently provided Decedent with "a generic contact with a Stanford switchboard" rather than one properly staffed with knowledgeable personnel (SAC ¶ 87), it is undisputed that Abbott had no involvement in or control over that emergency phone number.

Plaintiffs emphasize that in the protocol for the clinical trial that Abbott submitted to the FDA, it supplied a *different* telephone number listed under the heading "EMERGENCY CONTACTS." (Righthand Decl. Ex. R, 51 ["The Thoratec HeartLine is available 24 hours a day for all device-related emergencies."].) As Plaintiffs concede, however, "There is no evidence the Decedent ever saw or knew about the Abbott number on the approved protocol." (Resp. to UMF 58.) That Abbott supplied a different telephone number to the FDA in its protocol that was not shared with Decedent or with other

[20] That handout bears a handwritten notation, evidently by Ms. Rodezno, that reads, "Dr. Richard Ha, my surgeon" and a telephone number. (Righthand Decl. Ex. EE.) Dr. Ha's phone number also appears in two places on Ms. Rodezno's informed consent form. (*Id.* at Ex. I, 20.)

participants in the clinical trial is not material to Abbott's motion, which is based on undisputed facts. Plaintiffs offer no authority for the proposition that a device manufacturer such as Abbott owes a duty to a patient in a clinical trial to provide her with an emergency telephone number. That is hardly surprising, since a patient such as decedent logically would look to her health care provider, not to a device manufacturer, for immediate medical assistance.[21] In any event, Plaintiffs make no meaningful attempt to connect Abbott's inclusion of an emergency contact number in a clinical protocol it submitted to the FDA for approval of an IDE to their claims against Abbott.

Plaintiffs rest their claims against Abbott relating to the Stanford emergency phone number squarely on their contention that Abbott and Stanford entered into a joint venture. (Opposition, 19 ["If Stanford and Abbott are joint venturers, they are effectively partners and jointly and severally liable for the negligence here," including "the incorrect emergency numbers provided to Decedent by Stanford."].) Plaintiffs assert that whether Abbott and Stanford entered into a joint venture presents an issue of fact. (*Id.* at 19-20.) The Court disagrees, and finds that the undisputed facts establish that no such joint venture was formed.

"A joint venture is an undertaking by two or more persons jointly to carry out a single business enterprise for profit." (*Weiner v. Fleischman* (1991) 54 Cal.3d 476, 482, quoting *Nelson v. Abraham* (1947) 29 Cal.2d 745, 749.) "There are three basic elements of a joint venture: the members must have joint control over the venture (even though they may delegate it), they must share the profits of the undertaking, and the members must each have an ownership interest in the enterprise." (*Orosco v. Sun-Diamond Corp.* (1997) 51 Cal.App.4th 1659, 1666 (cleaned up).) "Whether the parties to a contract have created a joint venture . . . depends upon their actual intention which must be determined in accordance with ordinary rules governing interpretation of contracts." (*County of Riverside v. Loma Linda University* (1981) 118 Cal.App.3d 300, 313.)

Here, the undisputed evidence is irreconcilable with Plaintiffs' claim that Abbott and Stanford

[21] California has adopted the learned intermediary doctrine, which applies when drugs or medical devices are supplied in the course of a doctor-patient relationship. That doctrine provides generally that a prescription drug or device manufacturer has no duty to ensure that a warning given a physician reaches the patient. (See *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65; *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 318-319; *Plenger v. Alza Corp.* (1992) 11 Cal.App.4th 349, 362 n.6.)

entered into a joint venture. The Clinical Trial Agreement between Abbott and Stanford specifically disclaimed any such relationship:

> [Stanford] is an independent contractor to [Abbott Defendants], and ***not a partner, agent, employee, representative or joint-venture*** of [Abbott Defendants]. . . . Except as set forth in this Agreement, no Party, or its employees, agents, or subcontractors, has any right or authority to bind or act on behalf of another Party without that other Party's written permission.

(UMF 62; Righthand Decl., Ex. N § 14.8 (emphasis added).) Contrary to Plaintiffs' unsupported assertion, that Agreement hardly "offers many interpretations." (Opposition, 20.) To the contrary, its plain language leaves no room for a trier of fact to find that, contrary to their explicit agreement, the parties entered into a joint venture. (See *County of Riverside,* 118 Cal.App.3d at 314 [finding no joint venture where provisions of affiliation agreement between university medical school and county hospital "make it unmistakably clear that it was not intended to be an agreement for the joint management and operation of the hospital" (cleaned up)].)

Here, just as in *County of Riverside*, which Plaintiffs ignore, "[t]here was no understanding concerning division of revenues or sharing of losses or of a right of joint control." (*Id.*) Rather, the relationship created by the agreement was limited to an agreement by Stanford to participate in a clinical study of Abbott's medical device that was "intended to advance scientific and medical knowledge, with a due regard for patient safety." (Righthand Decl. Ex. N, 1.) Abbott agreed to provide the required quantities of devices and other materials needed by Stanford to conduct the study in accordance with the protocol. (*Id.* § 2.4.) The Agreement does not contemplate that the study will generate "revenues" or "profits," much less embody any agreement to share in such revenues or profits. To the contrary, the Agreement explicitly states that Stanford will be compensated for its performance of the study in accordance with an attached budget and payment that requires Abbott to pay Stanford certain fees for administrative and other costs, together with per patient costs. (*Id.* § 4.1 & Ex. A ["Reimbursement"].) The Agreement recites Stanford's representation that "its compensation under this Agreement is reasonable and consistent with fees charged for similar research in [its] geographical area, has been negotiated at arms-length, and is unrelated to the volume or value of any referrals or other business otherwise generated between [Abbott] and [Stanford]." (*Id.* § 4.2.)[22]

[22] The testimony of Abbott's PMK witness upon which Plaintiffs rely does not support their position. To

Thus, the unambiguous language of the Clinical Trial Agreement conclusively negates Plaintiffs' joint venture claim, and Abbott is entitled to summary adjudication. (See also, e.g., *Orosco v. Sun-Diamond Corp.* (1997) 51 Cal.App.4th 1659, 1666 [affirming summary judgment where there was "no evidence" that defendants agreed to share in the profits of the enterprise]; *Prostar Wireless Group, LLC v. Domino's Pizza* (N.D. Cal. 2018) 360 F.Supp.3d 994, 1008-1010 [granting summary judgment where there was no evidence that the defendants "expressly agreed (either orally or in writing) to begin a joint venture" and "a reasonable fact finder could not conclude that the parties came to an agreement to share profits or that they exercised joint control."].)

CONCLUSION

Defendants Abbott Cardiovascular Systems Inc., Thoratec LLC, and Thoratec Corporation's motion for summary adjudication is granted.

IT IS SO ORDERED.

Dated: May 7, 2026

Ethan P. Schulman
Judge of the Superior Court

be sure, Stanford received various payments under the Clinical Trial Agreement for its participation in the clinical trial, it shared a common goal with Abbott of prolonging patients' life expectancy, and Abbott would not have received FDA approval through a PMA, and therefore would not be in a position to sell its product commercially, had it not conducted a successful clinical trial. (Righthand Decl. Ex. H, 242-254.) Those unremarkable facts, however, do not establish any of the elements of a joint venture: there is no evidence of any agreement between Abbott and Stanford to share profits, to exercise joint control, or to share ownership. The testimony therefore cannot give rise to disputed issues of fact regarding the formation of a joint venture.

CERTIFICATE OF ELECTRONIC SERVICE

(CCP 1010.6, and CRC 2.251)

I, Edward Santos, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On May 7, 2026, I electronically served:

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY ADJUDICATION

via File & ServeXpress on the recipients designated on the Transaction Receipt located on the File & ServeXpress website.

Date: MAY 07 2026

Brandon E. Riley, Court Executive Officer

By: Edwan =/. SL

Edward Santos, Deputy Clerk