NOT FOR PUBLICATION

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MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

SARA EBRAHIMI, Plaintiff-Appellant, v. MENTOR WORLDWIDE LLC, Defendant-Appellee, and JOHNSON & JOHNSON SERVICES, INC, Defendant.	No. 19-55103 D.C. No. 2:16-cv-07316-DMG-KS MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Dolly M. Gee, District Judge, Presiding

Submitted May 12, 2020**
Pasadena, California

Before: COOK,*** MURGUIA, and OWENS, Circuit Judges.

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* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

*** The Honorable Deborah L. Cook, United States Circuit Judge for the U.S. Court of Appeals for the Sixth Circuit, sitting by designation.

Sara Ebrahimi appeals from the district court's judgment dismissing her action against Mentor Worldwide LLC ("Mentor"). Ebrahimi alleged a state law claim for strict product liability (manufacturing defect) arising out of injuries Ebrahimi suffered after the implantation of silicone gel breast implants manufactured by Mentor. The breast implants at issue are a Class III medical device approved by the Federal Drug Administration ("FDA") under the pre-market approval process of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. We review de novo a district court's dismissal for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). *Puri v. Khalsa*, 844 F.3d 1152, 1157 (9th Cir. 2017). As the parties are familiar with the facts, we do not recount them here. We affirm.

The district court properly held that Ebrahimi's state law manufacturing defect claim was expressly preempted by the MDA. The MDA expressly preempts state law claims unless they are premised on a "parallel" federal requirement. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *see also* 21 U.S.C. § 360k(a). In other words, "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." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019).

Ebrahimi argues that she adequately alleged that Mentor violated the FDA's Current Good Manufacturing Practices or "CGMPs," which "establish[] basic requirements applicable to manufacturers of finished medical devices." 21 C.F.R. § 820.1; *see also Weber*, 940 F.3d at 1113-14. Ebrahimi essentially contends that the court can plausibly infer that Mentor must have violated at least one of the FDA's CGMPs by not catching her allegedly defective implants. However, even if more general FDA requirements are sufficient for a parallel claim, mere allegations "suggesting that [Ebrahimi's] particular breast implant[s] w[ere] defective do[] not show that [Mentor] failed to comply with the FDA's Current Good Manufacturing Practices." *Weber*, 940 F.3d at 1114. Further, contrary to Ebrahimi's characterization, Mentor's Product Insert Data Sheet does not reflect that the FDA-approved implants had some design specification or manufacturing requirement that would only allow an "extremely low level of gel bleed" with "no clinical consequence."

While we are sympathetic to Ebrahimi's health problems, she has not sufficiently alleged that Mentor violated an FDA requirement when it manufactured her implants. Accordingly, the district court properly dismissed Ebrahimi's state law manufacturing defect claim as expressly preempted by the MDA.

AFFIRMED.