

1 Plaintiffs filed a form complaint on June 4, 2014 in Fresno County Superior Court in
2 which they indicated this is a products liability/personal injury action. (Doc. No. 1-1 at 6.) The
3 action was removed to this federal court by defendant on May 27, 2015 on the basis of diversity
4 jurisdiction under 28 U.S.C. § 1332. (Doc. No. 1.) This court has jurisdiction pursuant to 28
5 U.S.C. §§ 1332 and 1446.

6 BACKGROUND

7 Because plaintiffs filed a form complaint in state court and did not amend the complaint
8 following removal of the action to federal court, neither factual details concerning plaintiffs'
9 claimed injuries nor specific legal theories of liability have been alleged in any detail. A brief
10 summary of the claims contained in the joint status report filed by the parties with the court
11 shortly after removal indicates that plaintiff Ruben Merancio seeks compensatory damages based
12 on allegedly defective artificial knee manufactured by defendant and implanted in him on June 4,
13 2012. (Doc. No. 10 at 2.) Ultimately, on summary judgment, plaintiffs have agreed with
14 defendant's characterization of their claims as being the following: "(1) Strict Products Liability
15 for Design Defect; (2) Strict Products Liability for Manufacturing Defect; (3) Breach of Implied
16 Warranty; (4) Negligence, and (5) Loss of Consortium." (Doc. No. 27 at ¶ 26.)²

17 In opposing the pending summary judgment motion plaintiffs have presented no
18 substantive evidence concerning the merits of their claims.³ Rather, plaintiffs' opposition is
19 premised solely on objections to certain portions of the evidence offered by defendant in support
20 of its motion for summary judgment. Moreover, plaintiffs' objections to defendant's evidence are

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22 ² In moving for summary judgment in its favor in this action, defendant also does so with respect
23 to any failure to warn claims plaintiff Mr. Merancio may be attempting to bring. (Doc. No. 25 at
24 24–26.) Defendant notes that failure to warn claims are commonly brought in these types of
25 cases. However, the court declines to address defendant's motion for summary judgment with
26 respect to a cause of action plaintiffs have disclaimed bringing, and so does not address failure to
27 warn.

26 ³ As noted in defendant's reply brief and confirmed at oral argument on the pending motion,
27 plaintiffs' counsel served no discovery requests on defendant in this action and disclosed no
28 expert witnesses. (Doc. No. 30 at 8.) The court is perplexed by the manner in which plaintiffs
have proceeded in this action and, in particular, by their complete failure to present any evidence
whatsoever in opposition to defendant's motion for summary judgment.

1 premised almost solely on purported violations of rules governing discovery. Because the court
2 finds plaintiffs’ objections to be meritless for the reasons explained below, the court treats
3 defendant’s statement of facts as undisputed. Defendant’s separate statement of uncontroverted
4 facts, as supported by the exhibits submitted with that statement, reflect the following. (*See* Doc.
5 No. 25-1, *et seq.*)

6 Plaintiff Ruben Merancio is approximately 61 years old, and previously worked at the
7 Wine Group Winery as a filter operator from September 1998 to 2014. Plaintiff Lupe Merancio
8 has been Mr. Merancio’s wife for over 25 years. Mr. Merancio underwent total knee
9 arthroplasty—a surgical replacement of the knee joint—on his left knee on June 5, 2006.
10 Beginning in 2009, Mr. Merancio again began having problems with his left knee, and was
11 ultimately advised by Dr. Kevin Lester that non-surgical treatments would not help the condition.
12 Mr. Merancio thereafter had revision surgery performed by Dr. Lester on his left knee on June 4,
13 2012. During that surgery, a knee system called the “Legion System,” which was manufactured
14 by defendant, was implanted to replace the artificial knee that had been implanted in 2006.

15 During follow-up medical appointments, Dr. Lester reviewed X-rays from both June 19,
16 2012 and October 16, 2012, which revealed no complications or indications that the newly
17 implanted device or surgery had failed. Nevertheless, Mr. Merancio claimed he experienced pain
18 in that knee following this 2012 surgery, and sought a second opinion in 2013 from a Dr.
19 Thomas. Dr. Thomas advised plaintiff that he needed another revision surgery, which Dr.
20 Thomas performed on October 28, 2013. As of August 9, 2016, Mr. Merancio was no longer
21 experiencing any problems with his left knee. However, the only evidence supporting plaintiffs’
22 claims against defendant Smith & Nephew, Inc.—disclosed to defendants pursuant to a discovery
23 request served on plaintiffs’ counsel —appears to be that plaintiff Mr. Merancio has stated merely
24 he “was told the hardware inserted in his knee failed.” (Doc. No. 25-11 at 4.) The discovery
25 response provided by plaintiffs specifies neither who told Mr. Merancio the artificial knee used in
26 his 2012 replacement surgery had failed nor when he was told that fact.

27 For its part, defendant has presented the following evidence in support of its pending
28 motion. Defendant located the lot numbers for the component pieces of the Legion System used

1 in Mr. Merancio’s 2012 knee revision. It determined these lot numbers were inspected during the
2 manufacturing process and were found to be compliant with defendant’s standard operating
3 procedures and quality control guidelines. Further, defendant retained Dr. Ian C. Clarke as an
4 expert witness, who specializes in the mechanical and bio-engineering aspects of orthopedic
5 devices. Dr. Clarke determined there was no evidence suggesting that the Legion components
6 manufactured by defendant and used in Mr. Merancio’s 2012 knee revision surgery were
7 involved in the apparent ultimate failure of that procedure.

8 **LEGAL STANDARD**

9 Summary judgment is appropriate when the moving party “shows that there is no genuine
10 dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R.
11 Civ. P. 56(a).

12 In summary judgment practice, the moving party “initially bears the burden of proving the
13 absence of a genuine issue of material fact.” *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387
14 (9th Cir. 2010) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). The moving party
15 may accomplish this by “citing to particular parts of materials in the record, including
16 depositions, documents, electronically stored information, affidavits or declarations, stipulations
17 (including those made for purposes of the motion only), admissions, interrogatory answers, or
18 other materials” or by showing that such materials “do not establish the absence or presence of a
19 genuine dispute, or that the adverse party cannot produce admissible evidence to support the
20 fact.” Fed. R. Civ. P. 56(c)(1)(A), (B). When the non-moving party bears the burden of proof at
21 trial, “the moving party need only prove that there is an absence of evidence to support the
22 nonmoving party’s case.” *Oracle Corp.*, 627 F.3d at 387 (citing *Celotex*, 477 U.S. at 325.). *See*
23 *also* Fed. R. Civ. P. 56(c)(1)(B). Indeed, summary judgment should be entered, after adequate
24 time for discovery and upon motion, against a party who fails to make a showing sufficient to
25 establish the existence of an element essential to that party’s case, and on which that party will
26 bear the burden of proof at trial. *See Celotex*, 477 U.S. at 322. “[A] complete failure of proof
27 concerning an essential element of the nonmoving party’s case necessarily renders all other facts
28 immaterial.” *Id.* In such a circumstance, summary judgment should be granted, “so long as

1 whatever is before the district court demonstrates that the standard for entry of summary
2 judgment . . . is satisfied.” *Id.* at 323.

3 If the moving party meets its initial responsibility, the burden then shifts to the opposing
4 party to establish that a genuine issue as to any material fact actually does exist. *See Matsushita*
5 *Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In either event, “[a] trial court
6 can only consider admissible evidence in ruling on a motion for summary judgment.” *Orr v.*
7 *Bank of America, NT & SA*, 285 F.3d 764, 773 (9th Cir. 2002). “In evaluating the evidence to
8 determine whether there is a genuine issue of fact,” the court draws “all reasonable inferences
9 supported by the evidence in favor of the non-moving party.” *Walls v. Central Costa County*
10 *Transit Authority*, 653 F.3d 963, 966 (9th Cir. 2011). Ultimately, the “purpose of summary
11 judgment is to ‘pierce the pleadings and to assess the proof in order to see whether there is a
12 genuine need for trial.’” *Matsushita*, 475 U.S. at 587 (citations omitted).

13 ANALYSIS

14 1. *Purported Violations of Discovery Rules Do Not Bar Consideration of Defendant’s* 15 *Evidence on Summary Judgment*

16 As noted above, plaintiffs oppose defendant’s motion only on the grounds that certain
17 evidence offered by defendant in support of its motion should be stricken and not considered by
18 the court because of defendant’s failure to comport with certain rules governing discovery. (Doc.
19 No. 26 at 2–4.) More specifically, plaintiffs maintain: (1) the declaration of Paul Crabtree, an
20 employee of defendant’s, should be stricken because defendant “failed to make timely Initial
21 Disclosures and failed to timely produce documents”; (2) the declaration of Dr. Clarke,
22 defendant’s retained expert, should be stricken because he failed to attach the facts and data
23 considered in forming his opinion to his declaration and because the list of cases in which he was
24 an expert was not disclosed; (3) Dr. Clarke’s opinion should be stricken because it was based in
25 part on an eleven-year-old study that did not include defendant’s components; and finally, (4) Dr.
26 Clarke’s opinion should be stricken because he is not a medical doctor. (*Id.*) These objections to
27 the declarations of Mr. Crabtree and Dr. Clarke will be addressed in turn below.

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1 a. Declaration of Paul Crabtree

2 Plaintiffs represent that defendant's initial disclosures were untimely in this case, and
3 therefore Paul Crabtree's declaration should be struck. (*See* Doc. No. 29 at ¶¶ 8–10.) According
4 to plaintiff, defendant's initial disclosures were due on October 28, 2015, which is the date
5 plaintiffs' initial disclosures were served. (Doc. No. 29 at ¶ 8.) When plaintiffs' counsel notified
6 defense counsel on March 3, 2016 that he had not received any initial disclosures, defense
7 counsel promptly responded by e-mail and then followed up with a hard copy of defendant's
8 initial disclosures on March 7, 2016. (Doc. No. 29 at ¶¶ 9, 10.) Defense counsel supplemented
9 defendant's initial disclosures on July 8, 2016, July 22, 2016, September 14, 2016, October 17,
10 2016, and November 15, 2016. (Doc. No. 29 at ¶¶ 14, 15, 17, 19, 20, 23.) Under this court's
11 amended scheduling order, non-expert discovery in this case closed September 11, 2016. (Doc.
12 No. 17.)

13 The sum total of plaintiffs' argument here is that "the declaration of Paul Crabtree should
14 be disregarded and stricken in it's [sic] entirety pursuant to FRCP 26(a)(1)(C) and 26(a)(1)(E)
15 and 26(g)(1)(A)⁴ and Rule 37(a)(4) and 37(c)(1) on the grounds that Defendant failed to make
16 timely Initial Disclosures and failed to timely produce documents." (Doc. No. 26 at 2.)⁵

17 Initial disclosures under Rule 26 are due "at or within 14 days after the parties' Rule 26(f)
18 conference unless a different time is set by stipulation or court order." Fed. R. Civ. P.
19 26(a)(1)(C). Parties must make their initial disclosures based on the information they have, and
20 are not excused from disclosure requirements simply because they have not fully investigated the

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22 ⁴ Rule 26(g)(1)(A) requires the signature of an attorney for the disclosing party on each
disclosure and every discovery request. It is not apparent why this is relevant here.

23 ⁵ Plaintiffs repeat these objections largely verbatim in their objections to plaintiff's separate
24 statement of facts. (*See* Doc. No. 27 at ¶¶ 1–11; Doc. No. 28.) These objections add little detail,
25 though they specify that Exhibits A and C to Crabtree's declaration should be stricken because
26 they were received on January 24, 2017 and October 17, 2016, respectively. (*See id.* at ¶¶ 5, 8.)
27 Defendant asserts it provided these documents to plaintiffs in supplemental disclosures on July
28 22, 2016 and October 17, 2016. (Doc. No. 30 at 9.) Regardless of when they were received,
plaintiffs provide no indication of how they were harmed by the purportedly late disclosures.
Given the court's determination that any untimely disclosures were harmless in this case, it need
not decide whether defendant's disclosures were, in fact, untimely.

1 case. Fed. R. Civ. P. 26(a)(1)(E). That is, at least in part, because Rule 26(e) also requires the
2 supplementation of any initial disclosures.

3 Rule 37 bars parties from using evidence that was improperly disclosed unless the failure
4 to follow the rule was harmless. Fed. R. Civ. P. 37(c)(1) (disallowing use “unless the failure was
5 substantially justified or harmless”). Here, defendant represents it complied with Rule 26, though
6 it does not state when its initial disclosures were provided to plaintiffs’ counsel. (Doc. No. 30 at
7 7.) Nevertheless, defendant notes it disclosed the identity of Crabtree in a supplemental initial
8 disclosure well prior to the close of discovery in this action, and that Crabtree was ultimately
9 deposed by plaintiffs. (Doc. No. 29-13 at 3 (disclosing Crabtree in supplemental disclosures
10 dated July 5, 2016); Doc. No. 29-14 at 2 (email from plaintiff’s counsel’s office seeking to
11 schedule deposition of Crabtree).) Plaintiffs have made no showing that they were prejudiced by
12 the timing of defendant’s disclosures. Indeed, plaintiffs have made no allegations of any harm—
13 not even general, vague, and conclusory ones—flowing from defendant’s allegedly belated
14 disclosures. Plaintiffs’ counsel confirmed at oral argument that Crabtree was deposed. *See El*
15 *Ranchito, Inc. v. City of Harvey*, 207 F. Supp. 2d 814, 818 (N.D. Ill. 2002) (declining to exclude
16 witnesses who were not timely disclosed because they were employees of plaintiff, not surprise
17 witnesses and were available for deposition and thus any delay in their disclosure was harmless);
18 *see also Wetz v. Target Corp.*, No. 08-CV-78 GSA, 2009 WL 651129, at *2 (E.D. Cal. Mar. 12,
19 2009).

20 Accordingly, the court finds that any delay in defendant’s supplementing of its initial
21 disclosures was harmless and declines to strike Crabtree’s declaration submitted in support of
22 defendant’s motion for summary judgment.

23 b. Declaration of Dr. Clarke

24 Plaintiffs have several different arguments as to why Dr. Clarke’s declaration, submitted
25 in support of defendant’s pending motion for summary judgment, should be stricken. Plaintiffs
26 assert, “the report of Ian Clarke, in it’s [sic] entirety, should be disregarded and stricken pursuant
27 to FRCP Rule 26(a)(2)(B), subsections ii and iii, FRCP Rule 26(a)(2)(B)(v), FRCP Rule 37(a)(4)
28 and 37(c)(1), Federal Rules of Evidence Rules 702 and 703.” (Doc. No. 26 at 2.) According to

1 plaintiffs, Dr. Clarke did not attach the necessary facts or data to his expert report, failed to
2 identify the other cases in which he has served as an expert, and other miscellaneous complaints
3 concerning the timeliness and sufficiency of his report. (*Id.* at 2–3; Doc. No. 29 at ¶ 23.)

4 Aside from the above complaints, plaintiffs’ other major objection is that Dr. Clarke is not
5 qualified under the Federal Rules of Evidence to assert certain opinions because he is not a
6 medical doctor. (*Id.*) Namely, plaintiffs complain about Dr. Clarke’s expressed opinions that:
7 Mr. Merancio “had bone insufficiency at the time of the June 2012 surgery”; “the radiographs
8 show the femoral and tibial components were smaller than desirable”; “the alleged fracture of the
9 wall of the posterior tibia ‘likely’ resulted during the June 2012 surgery”; and that Mr.
10 Merancio’s “complaints of pain are sufficient to presume the ‘fixation was not truly adequate.’”
11 (*Id.*) None of these issues provide any basis to exclude the defense expert’s testimony.

12 i. *Inadequate Disclosures*

13 Under Rule 26, “a party must disclose to the other parties the identity of any witness it
14 may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705.” Fed. R.
15 Civ. P. 26(a)(2)(A). The rule specifies which experts must file a written report and what must be
16 included in such a report, namely the facts or data considered by the witness and a list of cases in
17 which the witness appeared as an expert within the last four years. Fed. R. Civ. P. 26(a)(2)(B).

18 Defendant maintains that the data and facts considered by the witness were included in Dr.
19 Clarke’s report. (Doc. No. 30 at 10.) Indeed, that expert report outlines what was reviewed by
20 Dr. Clarke in drawing his conclusion. (*See* Doc. No. 25-17 at 2.) It also contains various charts
21 and graphs which reflect a citation to an article disclosed to plaintiffs in a supplemental initial
22 disclosure dated November 15, 2016. (*See id.* at 4–5; Doc. No. 29-19.) It is true that the article
23 referred to was included in a supplemental initial disclosure which was made by defendant three
24 days after the expert disclosure deadline in this action. However, once again, plaintiffs have not
25 suggested in any way that they were harmed or prejudiced by any delay in disclosing this
26 information.

27 It does appear that Dr. Clarke failed to include a list of cases in which he has appeared as
28 an expert in the last four years in his report. However, it is also the case that plaintiffs’ counsel

1 never asked defense counsel or the expert for this list and never filed a motion to compel with the
2 court seeking the information or the imposition of sanctions. Similarly, plaintiffs' counsel did not
3 seek further information about Dr. Clarke's reference in his report to the "Smith & Nephew
4 Website for Legion knee components." Again, plaintiffs do not even generally suggest how they
5 have been harmed as a result of these minor deficiencies in Dr. Clarke's expert report. Indeed,
6 when asked at the hearing on the pending motion, plaintiffs' counsel suggested he purposefully
7 did not pursue any further efforts to obtain the list of cases in which Dr. Clarke had appeared as
8 an expert because, in counsel's view, it made defendant's expert "attackable." Striking the
9 declaration of defendant's expert under these circumstances would be far too harsh a sanction,
10 especially when plaintiffs never diligently pursued the information they now seek to complain
11 about. *See Harvey v. District of Columbia*, 949 F. Supp. 874, 877 (D.D.C. 1996) (declining to
12 strike expert testimony where the party claiming prejudice failed to file a motion to compel and
13 waited until the day before the close of discovery to raise issues regarding the inadequacy of the
14 expert's report). While plaintiffs' counsel may have had tactical reasons for choosing not to
15 pursue a motion to compel, such a choice belies any claim that plaintiffs' case was actually
16 harmed by the failure of defendant's expert to provide a list of cases in which he had appeared as
17 an expert as part of his report. *See Casida v. Sears Holdings Corp.*, No. 1:11-cv-01052 AWI JLT,
18 2012 WL 3260423, at *3-4 (E.D. Cal. Aug. 8, 2012) (refusing to strike a witness who had failed
19 to appear at deposition when the party had failed to file motion to compel); *Holt v. Wesley Med.*
20 *Ctr., LLC*, No. 00-1318-JTM, 2006 WL 5556006, at *4-5 (D. Kan. Jan. 25, 2006) (refusing to
21 strike expert witness for failure to disclose case list when party failed to file a motion to compel).⁶

22 ⁶ The striking of experts is a very harsh penalty, and other sanctions and/or remedies for any
23 harm suffered should first be considered. *See, e.g., Herron v. Smith & Nephew, Inc.*, No. 2:12-cv-
24 3052-LKK-KJN, 2014 WL 3058458, at *3 (E.D. Cal. July 3, 2014) ("[B]ecause striking the
25 experts would be a very harsh penalty, likely crippling plaintiff's case, the court concludes that
26 lesser measures should first be attempted."); *Horn v. Hornbeak*, No. 1:08cv1622 LJO DLB, 2010
27 WL 960364, at *2 (E.D. Cal. Mar. 16, 2010) (describing striking defendant's only expert as
28 "especially harsh"); *I-Flow Corp. v. Apex Med. Techs., Inc.*, No. 07cv1200-DMS (NLS), 2009
WL 8575332, at *2 (S.D. Cal. Apr. 24, 2009) ("[T]he absence of any prejudice would render the
remedy of striking the [expert] reports unduly harsh and not in compliance with Rule 37 of the
Federal Rules of Civil Procedure."). Given the apparent harmlessness in this case, striking the
expert's declaration in support of defendant's summary judgment motion is unwarranted.

1 Finally, to the extent plaintiffs contest the relevance of a study on which the defense
2 expert relied—either because it was eleven years old or because it purportedly failed to include
3 relevant examples of various parts—these are topics which go to the weight of that evidence,
4 rather than a reason to strike the expert’s declaration. Of course, as noted above, plaintiffs have
5 come forward with no evidence in opposition to the pending summary judgment motion.

6 ii. *Disqualification of Expert*

7 Rule 702 of the Federal Rules of Evidence dictates which witnesses may testify as an
8 expert, and generally notes witnesses may be qualified as experts “by knowledge, skill,
9 experience, training, or education.” Fed. R. Evid. 702. Plaintiffs argue that Dr. Clarke is not a
10 medical doctor and is, therefore, not qualified to render several opinions expressed in his report.
11 (*See* Doc. No. 26 at 3.) However, plaintiffs have failed to present any argument or authority in
12 support of this contention. Dr. Clarke’s résumé indicates he holds a bachelor’s degree in
13 mechanical engineering and a doctorate in bioengineering, has worked in numerous academic and
14 research positions concerning orthopedics, previously served as the president of an orthopedic
15 implant company, and continues to work in research related to mechanical and bioengineering of
16 orthopedic joint replacements. (*See* Doc. No. 25-16 at 7–9.) Dr. Clark is also an author of
17 numerous journal articles in that field. (*Id.* at 10–12.) Given this extensive background, there is
18 no apparent reason why Dr. Clarke should be found unqualified to provide an expert opinion on
19 the likely cause of a knee replacement failure. *See Speaks v. Mazda Motor Corp*, 118 F. Supp. 3d
20 1212, (D. Mont. 2015) (admitting biomechanical engineer opinion testimony with respect to how
21 plaintiff sustained her injuries in a motor vehicle accident allegedly caused by a defective design);
22 *see also In re Zimmer Nexgen Knee Implant Products Liability Litigation*, MDL No. 2272, No. 12
23 C 6279, 2015 WL 3669933, at *19 (N.D. Ill. June 12, 2015) (referring to one of defendant’s
24 experts as a biomechanical engineer). Certainly plaintiffs have provided no basis for so finding.
25 Accordingly, their argument in this regard will be rejected.

26 2. *Defendant’s Motion for Summary Judgment*

27 The court will now turn to the substance of defendant’s motion for summary judgment.
28 As noted, only a brief form complaint was filed by plaintiffs in state court generically alleging

1 claims described as for personal injury / products liability. (Doc. No. 1-1 at 6.) Nevertheless, and
2 out of an abundance of caution, the court will construe the complaint as alleging five separate
3 causes of action: (1) strict products liability for design defect; (2) strict products liability for
4 manufacturing defect; (3) breach of implied warranty; (4) negligence; and (5) loss of consortium.
5 (See Doc. No. 27 at ¶ 26) (plaintiffs agreeing that this accounting of their causes of action by
6 defendant was “undisputed”). Above, the court has already found plaintiffs’ evidentiary
7 objections to defendant’s evidence to be meritless. Accordingly, the court will treat all of the
8 facts presented by defendant as undisputed, since plaintiffs have offered no admissible evidence
9 bearing on any issue of fact—material or otherwise—relevant to the resolution of the pending
10 motion. Based upon the evidence before the court and for the reasons set forth below, the court
11 concludes defendant is entitled to summary judgment in its favor as to each of plaintiffs’ claims.⁷

12 a. There is No Evidence of a Manufacturing Defect

13 Defendant argues that because it is undisputed it complied with federal manufacturing
14 standards and plaintiffs have proffered no evidence of a manufacturing defect, plaintiffs will be

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18 ⁷ Because the court is not persuaded by defendant’s preemption argument, each of plaintiffs’
19 claims must be addressed. In this regard, products admitted to market by the FDA through the
20 § 510(k) process generally do not undergo a device-specific review, but rather are exempted from
21 such review. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008) (“*Riegel*”); *Medtronic, Inc.*
22 *v. Lohr*, 518 U.S. 470, 493–94 (1996) (“*Lohr*”). In the absence of device-specific requirements,
23 the express preemption provision of the Medical Device Amendments of 1976 does not prevent
24 products liability suits under state law. See 21 U.S.C. § 360k; *Riegel*, 552 U.S. at 322; *Lohr*, 518
25 U.S. at 493–94. Defendant submits evidence that the Class II device at issue here was brought to
26 market under the § 510(k) process, essentially receiving an exemption from federal scrutiny. (See
27 Doc. No. 25-2 at 6–7.) Because defendant’s evidence shows the product was not subject to any
28 device-specific requirements, preemption is inapplicable here. *Papike v. Tambrands Inc.*, 107
F.3d 737, 740–41 (9th Cir. 1997) (noting that where the FDA promulgated product and disease
specific regulations with respect to a Class II device, preemption could be found); *Anguiano v.*
E.I. Du Pont De Nemours & Co., Inc., 44 F.3d 806, 810 (9th Cir. 1995) (“Class II devices . . .
must carry some specific regulation beyond the identification regulation for preemption to
apply.”); *Jones v. Medtronic*, 89 F. Supp. 3d 1035, 1045–46 (D. Ariz. 2015) (noting the “510(k)
process may meet the first prong of *Riegel* if the FDA imposes requirements specific to the
device,” but “general regulations for Class II devices do not rise to the level to cause preemption
under the MDA”) (quoting *Brown v. Medtronic, Inc.*, 852 F. Supp. 717, 720–21 (S.D. Ind. 1994)).

1 unable to meet their burden of proof at trial to establish that there was a manufacturing defect.⁸
2 (Doc. No. 25 at 19–20.) It is undisputed on summary judgment that, at the time the parts used in
3 Mr. Merancio’s knee replacement left the control of defendant, they had been inspected, passed
4 quality control inspections, and were in compliance with all applicable FDA regulations. (Doc.
5 No. 25-2 at ¶¶ 10–11; Doc. No. 27 at ¶¶ 37–39.) Showing the product had a defect when it left
6 the manufacturer is a necessary element of plaintiff’s manufacturing defect claim. *See Jian Wu v.*
7 *Ean Holdings LLC*, Case No. 5:13-cv-00188-PSG, 2014 WL 117338, at *2 and n.14 (N.D. Cal.
8 Jan. 10, 2014) (citing Judicial Council of California Jury Instruction 1201—Manufacturing
9 Defect—Essential Factual Elements).

10 Here, plaintiff has presented no admissible evidence establishing the existence of a
11 genuine dispute of material fact about the existence of a manufacturing defect in the artificial
12 knee used in Mr. Merancio’s 2012 knee replacement surgery. *See Oracle Corp.*, 627 F.3d at 387
13 (“[T]he moving party need only prove that there is an absence of evidence to support the
14 nonmoving party’s case.”). Accordingly, defendant is entitled to summary judgment in its favor
15 as to this claim.

16 b. Plaintiff’s Design Defect Claim is Barred as a Matter of Law

17 According to defendant, any design defect claim plaintiffs are alleging is barred as a
18 matter of California law. (Doc. No. 25 at 20–21.) When an implantable medical device is only
19 available through a physician, by prescription, and is not sold directly to consumers, the
20 manufacturers of the device “are immune from design defect strict liability.” *Artiglio v. Superior*
21 *Court of San Diego Cty.*, 22 Cal. App. 4th 1388, 1397 (1994). The only relevant fact-finding is

23 ⁸ Defendant argues that a manufacturing defect claim with respect to a medical device may not
24 be maintained without the actual device in issue. (*See* Doc. No. 25 at 19) (“Because the removed
25 Legion System cannot be examined, Merancio cannot, by California law, prove a manufacturing
26 defect.”). However, defendant has cited no persuasive authority in support of this argument.
27 While it would presumably be easiest to demonstrate a product defect by a direct examination of
28 that product, circumstantial evidence is a generally accepted means for a party to meet its burden
of proof. *See Notmeyer v. Stryker Corp.*, 502 F. Supp. 2d 1051, 1059 (N.D. Cal. 2007) (The rule
under California law that a design defect must be affirmatively established and that an inference
of defect cannot be drawn solely from the fact of an accident, “does not preclude a plaintiff from
proving a manufacturing defect using only circumstantial evidence.”)

1 whether the medical device was “physician-directed and physician-applied.” *Id.*; see also *Hufft*
2 *v. Horowitz*, 4 Cal. App. 4th 8, 19–20 (1992) (“[A] manufacturer is not strictly liable for injuries
3 caused by an implanted prescription medical product which has been (1) properly made and (2)
4 distributed with information regarding risks and dangers of which the manufacturer knew or
5 should have known at the time.”); *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086-YGR,
6 2013 WL 1149717, at *4–7 (N.D. Cal. Mar. 19, 2013) (concluding strict liability design defect
7 claims are “precluded as a matter of California law”).

8 It is undisputed on summary judgment in this case that the device at issue is available only
9 by prescription and is sold only to physicians, who then install the device in patients such as Mr.
10 Merancio. (Doc. No. 25-2 at ¶¶ 3, 9.) Plaintiff’s strict liability design defect claims are therefore
11 barred as a matter of California law and defendant is entitled to summary judgment in its favor as
12 to this claim.⁹

13 c. Summary Judgment is Appropriate on Plaintiff’s Negligence Claim

14 Defendant argues plaintiff’s negligence claim fails because there is no evidence defendant
15 breached a duty or that any action of defendant’s caused Mr. Merancio’s injury. (Doc. No. 25 at
16 22–23.) “The elements of a negligence cause of action are the existence of a legal duty of care,
17 breach of that duty, and proximate cause resulting in injury.” *McIntyre v. Colonies-Pacific, LLC*,
18 228 Cal. App. 4th 664, 671 (2014) (quoting *Castellon v. U.S. Bancorp*, 220 Cal. App. 4th 994,
19 998 (2013)). To establish causation, a plaintiff must show a defendant’s “negligence ‘was a
20 substantial factor in bringing about the injury.’” *Sandoval v. Bank of America*, 94 Cal. App. 4th
21 1378, 1386 (quoting *Saelzler v. Advanced Group 400*, 25 Cal. 4th 763, 778 (2001)) (internal
22 quotations omitted).

23 Defendant argues that, because it complied with all applicable federal regulations and has
24 come forward with evidence that there was no defect in either manufacturing or design of its
25 artificial knee, it did not breach its duty to plaintiff. The court rejects the first aspect of

27 ⁹ Because the court determines that plaintiff Ruben Merancio’s strict liability design defect claim
28 is barred as a matter of California law, it does not reach defendant’s alternative argument that
plaintiff lacks any evidence showing a design defect in the product. (See Doc. No. 25 at 21–22.)

1 defendant's argument in this regard. Arguing that no breach occurred simply because of
2 compliance with federal regulations would appear to merely be the flip side of defendant's
3 preemption argument which the court has already rejected by the court. *See* n. 7, above.
4 However, in moving for summary judgment defendant has presented uncontroverted evidence in
5 the form of the expert opinion of Dr. Clarke, who concluded "there is no evidence to suggest that
6 the Legion components used in Mr. RB. Merancio were likely involved in this short-term failure."
7 (Doc. No. 25-17 at 7.) Lacking any evidence from plaintiffs to the contrary, the court must
8 conclude that defendant is entitled to summary judgment in its favor with respect to plaintiff Mr.
9 Merancio's negligence claim. *See Celotex*, 477 U.S. at 322 ("[A] complete failure of proof
10 concerning an essential element of the nonmoving party's case necessarily renders all other facts
11 immaterial."); *see also Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc.*, 210 F.3d 1099,
12 1102 (9th Cir. 2000) (noting that where moving party does not have burden of proof at trial, it
13 need only "show that the nonmoving party does not have enough evidence of an essential element
14 to carry its ultimate burden of persuasion at trial").

15 d. Summary Judgment is Appropriate on the Breach of Warranty Claim

16 Defendant argues for summary judgment in its favor on plaintiff's breach of warranty
17 claim because such a claim only provides recovery for damage to the warrantied product itself,
18 which plaintiff does not seek. (Doc. No. 25 at 23.) Defendant's argument finds support under
19 California law. *See Jiminez v. Superior Court of San Diego Cty.*, 29 Cal. 4th 473, 483 (2002)
20 (distinguishing property damage recovery available in a strict liability defect case from that
21 available under contractual warranties, which "governs damage to the product itself"). Here,
22 plaintiff seeks general damages for pain, suffering, and inconvenience, and special damages for
23 medical expenses, future medical expenses, loss of earnings, and loss of future earning capacity.
24 (Doc. No. 25-6.) No amount is sought in property damage. (*Id.*) The damages Mr. Merancio
25 seeks here are generally not cognizable in claims sounding in contract in California. *See Quigley*
26 *v. Pet, Inc.*, 162 Cal. App. 3d 877, 887 (1984) ("[D]amages for pain and suffering or medical
27 expenses are ordinarily not available for breach of a commercial contract."); *see also Seely v.*
28 *White Motor Co.*, 63 Cal. 2d 9, 14-19 (1965) (breach of warranty claim "can properly include lost

1 profits as well as the amount paid on the purchase price”). Moreover, a plaintiff pursuing a
2 breach of warranty claim must generally demonstrate the existence of the warranty, its breach,
3 and losses proximately caused by the breach. *Pisano v. American Leasing*, 146 Cal. App. 3d 194,
4 198 (1983). Here, defendant has presented uncontroverted expert testimony that no defect in
5 defendant’s product was involved in the failure of Mr. Merancio’s 2012 knee replacement
6 surgery. (Doc. No. 25-17 at 7.)

7 For both of these reasons, the court concludes that defendant is entitled to summary
8 judgment in its favor as to plaintiff Mr. Merancio’s breach of warranty claim.¹⁰ *See Celotex*, 477
9 U.S. at 322; *Oracle Corp.*, 627 F.3d at 387; *Nissan Fire & Marine Ins. Co., Ltd.*, 210 F.3d at
10 1102.

11 e. Loss of Consortium

12 “Loss of consortium is not a derivative cause of action. While the cause of action is
13 triggered by the spouse’s injury, a loss of consortium claim is separate and distinct.” *Leonard v.*
14 *John Crane, Inc.*, 206 Cal. App. 4th 1274, 1279 (2012) (internal quotations omitted). “[E]ach
15 spouse has a cause of action for loss of consortium . . . caused by a negligent or intentional injury
16 to the other spouse by a third party.” *Id.* at 1282–83 (quoting *Rodriguez v. Bethlehem Steel*
17 *Corp.*, 12 Cal. 3d 382 (1974)). Nonetheless, while separate, a cause of action for loss of
18 consortium “is still ‘by its nature, dependent on the existence of a cause of action for tortious
19 injury to a spouse . . . , [and] it stands or falls based on whether the spouse of the party alleging
20 loss of consortium has suffered an actionable tortious injury. [Citations].” *Id.* at 1288 (quoting
21 *Hahn v. Mirda*, 147 Cal.App.4th 740, 746 (2007)).

22 As discussed above, here, plaintiffs have produced no evidence on summary judgment in
23 support of their claim that defendant negligently injured Mr. Merancio. *See Celotex*, 477 U.S. at
24 322; *Oracle Corp.*, 627 F.3d at 387; *Nissan Fire & Marine Ins. Co., Ltd.*, 210 F.3d at 1102.
25 Moreover, plaintiffs do not allege any intentional injury in the complaint. Therefore, defendant is
26

27 ¹⁰ Because defendant is entitled to summary judgment in its favor on plaintiff’s breach of
28 warranty claim for these reasons, the court need not reach defendant’s argument concerning the
lack of vertical privity between the parties. (*See* Doc. No. 25 at 23–24.)

1 entitled to summary judgment in its favor with respect to plaintiffs' loss of consortium claim.

2 **CONCLUSION**

3 For the reasons set forth above:

- 4 1. The Doe defendants are dismissed from this action;
- 5 2. Plaintiffs' requests to strike evidence presented by defendant in support of its motion
- 6 for summary judgment is denied;
- 7 3. Defendant's motion for summary judgment (Doc. No. 25) is granted;
- 8 4. The previously scheduled trial date of September 6, 2017, is vacated; and
- 9 5. The Clerk of the Court is directed to close this case.

10 IT IS SO ORDERED.

11 Dated: May 23, 2017

12 
UNITED STATES DISTRICT JUDGE

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