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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
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9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX-DGC

11 _____
12 Lisa Hyde and Mark E. Hyde, a married
couple,

No. CV-16-00893-PHX-DGC

13 Plaintiffs,

ORDER

14 v.

15 C. R. Bard, Inc., a New Jersey corporation;
16 and Bard Peripheral Vascular, Inc., an
Arizona corporation,

17 Defendants.
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20 The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether jury trial
21 on September 18, 2018. Defendants seek reconsideration of the Court's summary
22 judgment ruling that Wisconsin's product liability statute, Wis. Stat. § 895.047, does not
23 create a rebuttable presumption that the Bard IVC filter is not defective. Doc. 12007
24 at 10-12. The issue was addressed by the parties in their trial briefs and proposed jury
25 instructions, and discussed at the final pretrial conference held on September 6, 2018.
26 *See* Docs. 12358 at 11-14, 12438 at 49, 12400 at 11-12. Defendants stated in their trial
27 brief that the issue warrants more detailed briefing (Doc. 12358 at 13), but made clear at
28 the pretrial conference that the materials submitted are sufficient. For the reasons stated

1 below, the Court will deny Defendants' request for reconsideration.

2 Section 895.047(3)(b) creates a rebuttable presumption that a product is not
3 defective if it complied with "relevant standards, conditions, or specifications adopted or
4 approved by a federal or state law or agency[.]" Defendants argued in their summary
5 judgment motion that the design of the Bard filter and the warnings provided with the
6 device are presumed to be non-defective because Bard complied with the FDA's 510(k)
7 process. Doc. 7359 at 12. The Court rejected this argument because 510(k) review
8 focuses on equivalence, not safety. Doc. 12007 at 11. The Court noted that Defendants
9 had cited no legal authority for the proposition that the presumption applies even if the
10 government standard is not safety. *Id.* at 12 n.4.

11 Defendants' recent briefing relies on *Kilty v. Weyerhaeuser Co.*, No. 16-CV-515-
12 WMC, 2018 WL 2464470 (W.D. Wis. June 1, 2018), a decision issued after summary
13 judgment briefing was complete. Defendants argue that it would be incorrect to conclude
14 that only safety regulations are entitled to the presumption of non-defectiveness under
15 § 895.047(3)(b), but *Kilty* did not consider this issue. The regulations in *Kilty* were safety
16 standards – regulations enacted by the National Institute of Occupational Safety and
17 Health and the U.S. Bureau of Mines concerning the performance and quality of
18 respiratory equipment used to protect workers against asbestos exposure. 2018 WL
19 2464470, at *3 (discussing regulations set forth in 30 C.F.R. 11 *et seq.*); *see also*
20 *Commercial Union Ins. Co. v. United States*, No. CIV.A. 87-3913, 1988 WL 92081, at *1
21 (E.D. La. Aug. 19, 1988) (explaining that "Title 30 of the Code of Federal Regulations
22 establishes a schedule for testing to insure compliance with safety standards").

23 The fact that the safety standards in *Kilty* were sufficient to meet § 895.047(3)(b)'s
24 "relevant standards" requirement, Defendants contend, "does not mean that 'safety' is a
25 necessary condition under the statute." Doc. 12358 at 12 n.17. But *Kilty* does not
26 address this issue one way or the other, and Defendants cite no authority holding that the
27 Wisconsin presumption arises from non-safety regulations. Surely the statute's reference
28 to "*relevant* standards, conditions, or specifications" requires some connection to the

1 alleged defect. Wis. Stat. § 895.047(3)(b) (emphasis added). For example, it would
 2 make no sense to hold that an auto manufacturer’s compliance with federally-
 3 promulgated fuel efficiency standards gives rise to a presumption of non-defectiveness in
 4 a roll-over case where the plaintiff claims that the car’s suspension was defective. *Kilty’s*
 5 reliance on federal regulations that clearly concerned the safety of respiratory equipment
 6 does nothing to suggest that this Court erred when it held that Defendants’ compliance
 7 with the 510(k) process does give rise to the statutory presumption. As the Court noted
 8 in its summary judgment ruling, other cases specifically have held that § 895.047(3)(b)
 9 creates no rebuttable presumption for medical devices cleared under 510(k) review
 10 because that review does not concern the safety of the product. *See Hall v. Boston Sci.*
 11 *Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D. W. Va. Feb. 27, 2015)
 12 (“510(k) is not a ‘relevant standard’ here. Section 895.047 concerns whether a defect
 13 rendered the product ‘unreasonably dangerous,’ § 895.047(1), and, as the Supreme Court
 14 has held, 510(k) compliance does not go to the safety of a product.”); *Williams v. Boston*
 15 *Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016)
 16 (same). The Court continues to find these cases persuasive.¹

17 Defendants argue that whether the presumption applies in this case, and whether
 18 Plaintiffs have overcome it, are questions of fact for the jury to decide. Doc. 12358 at 13
 19 n.18. Defendants cite language from the Wisconsin model jury instruction, Wis JI-Civil
 20 § 3260.1, stating that the jury “must resolve this conflict.” *Id.* But the “conflict” referred
 21 to is not whether the rebuttable presumption has arisen, but whether it has been
 22 overcome. *See* Doc. 12438 at 49 (quoting Wis JI-Civil § 3260.1 (“There was evidence
 23 received that at the time of sale, the product complied in material respects with relevant
 24 standards . . . adopted or approved by a federal or state law or agency. From this

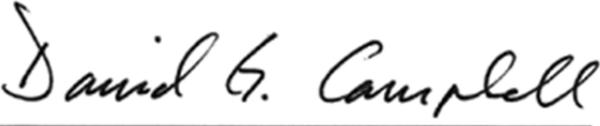
25
 26 ¹ Defendants contend that it would be unfair for Plaintiffs to argue that Defendants
 27 are liable for negligence per se based on violations of the “safety” standards set forth in
 28 FDCA and its implementing regulations if Defendants are precluded from relying on the
 same standards for purposes of § 895.047(3)(b). Doc. 12358 at 13. This issue is moot
 because the Court has entered judgment in favor of Defendants on the negligence per se
 claim. Doc. 12589.

1 evidence, a rebuttable presumption arises that the product was not defective. However,
2 there is also evidence which may be believed by you that the product is defective. You
3 must resolve this conflict.”)). Whether a defendant complied in material respects with
4 the government standard may also create a triable issue of fact. *See Merryfield v. KLI,*
5 *Inc.*, No. 17-C-742, 2018 WL 4178178, at *4 (E.D. Wis. Aug. 30, 2018) (denying
6 summary judgment in part because the jury reasonably could find that the product was
7 not made according to government specifications).

8 But whether the government standard is one from which a rebuttable presumption
9 may arise in the first instance – that is, whether it is a “relevant” standard for purposes of
10 § 895.047(3)(b) – is a question of law for the court. *See Williams*, 2016 WL 1448860,
11 at *3 (finding as a matter of law that § 895.047(3)(b) creates no presumption of non-
12 defectiveness for medical devices cleared under 510(k) review because that review does
13 not concern the safety of the product); *Kilty*, 2018 WL 2464470, at *3 (finding that the
14 presumption arose where the government issued specific safety regulations and certified
15 the manufacture’s compliance). Addressing that question of law, the Court again
16 concludes that the 510(k) process, which looked at substantial equivalence rather than
17 safety, and did not otherwise approve or certify the design of the Bard filter, is not a
18 relevant standard for purposes of the presumption in § 895.047(3)(b). The Court will not
19 instruct the jury that the presumption exists in this case.

20 **IT IS ORDERED** that Defendants’ request for reconsideration (Doc. 12358
21 at 11-14) is **denied**.

22 Dated this 13th day of September, 2018.

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26 David G. Campbell
27 Senior United States District Judge
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