[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
MARCH 30, 2009
THOMAS K. KAHN
CLERK

No. 08-13693

D. C. Docket No. 06-01281-CV-ORL-18KRS

UNITED STATES OF AMERICA,

Plaintiff-Counter
Defendant-Appellant-
Cross-Appellee,

versus

ENDOTEC, INC.,
a corporation,
MICHAEL J. PAPPAS,
FREDERICK F. BUECHEL,
an individual,

Defendants-Counter
Claimants-Appellees
Cross-Appellant.

Appeals from the United States District Court
for the Middle District of Florida

(March 30, 2009)

Before HULL, WILSON and HILL, Circuit Judges.

WILSON, Circuit Judge:

Pursuant to the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c, *et seq*., to the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*., the Food & Drug Administration ("FDA") regulates the introduction of medical devices into interstate commerce by requiring that a device meets certain rigorous standards. The United States of America ("Government") filed a civil action seeking a permanent injunction against Endotec, Inc. and its two owners, Michael Pappas and Frederick F. Buechel[1] (collectively, "Appellees"), alleging that they (1) manufactured and distributed adulterated ankle, knee, and jaw devices and (2) exceeded the scope of an approved clinical study of an ankle device, all in violation of the FDCA. In response, the Appellees assert that the ankle, knee, and jaw devices fall under the custom device exemption to the FDCA requirements and that they took certain remedial measures to cure any violations of the clinical study. After a three-day bench trial, the district court enjoined the Appellees from manufacturing and distributing the knee devices but rejected the Government's

[1] On appeal, both parties spell his name "Buechel." While the district court did the same in its caption, it spelled his name "Beuchel" throughout the text of its Order. *See United States v. Endotec, Inc.*, No. 6:06-cv-1281-Orl-18KRS, 2008 WL 1909164, at *1 (M.D. Fla. Apr. 30, 2008). We will refer to him as "Buechel."

requests to enjoin the manufacture and distribution of the ankle and jaw devices. *See Endotec, Inc.*, 2008 WL 1909164, at *14-15. The district court also found that the Appellees had not violated the investigational study of the ankle device. *See id.* The Government appealed as to the ankle and jaw devices and the Appellees cross-appealed as to the knee device.

For the reasons that follow, we affirm the district court's order as to the knee and jaw devices but reverse as to the ankle device and remand with instructions to the district court to enter a permanent injunction in favor of the Government.

I.

A. Statutory scheme

In 1976, Congress passed the MDA, which amended the FDCA and imposed a regime of detailed federal oversight for medical devices. The MDA divided medical devices into three classes "based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). Class I devices, such as tongue depressors and examination gloves, are subject to "general controls" including labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class II devices, such as oxygen masks and powered wheelchairs, are subject to "special controls" including performance standards and postmarket surveillance measures. *Id*. § 360c(a)(1)(B). Class III devices, such as pacemakers and replacement heart valves, are subject to

"premarket approval to provide reasonable assurance of its safety and effectiveness." *Id*. § 360c(a)(1)(C).

Medical devices in interstate commerce at the time of the passage of the MDA were grandfathered and allowed to remain on the market unless and until the FDA promulgated a regulation requiring premarket approval. *See id*. § 360e(b)(1)(A). Generally, any medical device introduced into interstate commerce for commercial distribution after the passage of the MDA is classified in Class III unless (1) the FDA promulgates a regulation classifying the device in Class I or Class II, or (2) the device is "substantially equivalent" to another pre-existing device on the market.[2] *Id*. § 360c(f)(1). Because all the medical devices at issue here were introduced into interstate commerce for commercial distribution after May 28, 1976, and because neither party asserts that the medical devices at issue have been reclassified or deemed substantially equivalent to a Class I or II device, they constitute Class III devices. *See* Tr. of R., Volume 6, at 10:23-24 (Testimony of Robert Gatling, Jr., Director of the Program Operations Staff, Office of Device Evaluation, Center for Devices and Radiological Health) (testifying that the

[2] The FDA's review for substantial equivalence is known as the "510(k)" process, named after the section of the MDA in which it can be found. "Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1004 (2008) (citing P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 992 (3d ed. 2007)).

medical devices "at issue in this case are all Class III devices").

The FDCA prohibits the introduction into interstate commerce of any adulterated or misbranded device. *See* 21 U.S.C. § 331(a), (k). To show a violation of § 331(a) and (k), the Government must prove: (1) Appellees' products are "devices" within the meaning of the FDCA; (2) the devices are adulterated or misbranded; and (3) the devices move in interstate commerce. A device is "adulterated" under the FDCA if it is required to receive premarket approval from the FDA but moves in commerce even though it did not receive premarket approval. *See id*. § 351(f)(1)(B). In other words, a Class III device moving in interstate commerce that has not received premarket approval constitutes an adulterated device.

The FDCA and MDA contain several exemptions, two of which arise in this case. First, the investigational device exemption ("IDE") allows an adulterated device to be distributed as part of a clinical investigation if certain conditions are met. *See id*. § 360j(g). Second, the custom device exemption exempts from performance standards and premarket approval requirements a device that meets the definition specified in the statute. *See id*. § 360j(b).

Lastly, section 332 of the FDCA provides that "[t]he district courts of the United States and the United States courts of the Territories shall have jurisdiction,

for *cause shown* to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j)." *Id*. § 332(a) (emphasis added).

B. Factual background

Endotec is a Florida corporation engaged in the business of manufacturing and distributing medical devices. Pappas is Endotec's President and co-owner, and Buechel is Endotec's Vice-President, medical director, and co-owner. The devices at issue include (1) ankle replacement implants with mobile bearings; (2) two types of mobile bearings used with knee replacement implants; and (3) a temporomandibular joint ("TMJ") implant, or a jaw device.

1. Ankle device

The Buechel-Pappas Total Ankle Replacement System ("B-P Ankle") is a generic mobile bearing device that consists of three components: (1) a tibial component; (2) a talar component; and (3) a mobile bearing between them.[3] Since 1991, Endotec has filed six "510(k)" applications with the FDA, asserting that the B-P Ankle is substantially equivalent to a Class II device. The FDA has rejected each submission. In October of 1997, Endotec received conditional approval for an IDE clinical study of the B-P ankle limited to two hospitals and ten patients. In May of 1999, the FDA granted full approval to Endotec's IDE clinical study of the

[3] The tibia is the shin bone and the talus is the bone at the top of the foot.

B-P Ankle, limited to 109 patients. The IDE reached full enrollment in September of 2001.

The ankle devices at issue here include (1) all ankle devices distributed by Endotec for use in patients beyond the scope of the IDE clinical study for the B-P Ankle, and (2) all ankle devices distributed by Endotec as "custom" or "surgeon specials." *See Endotec*, 2008 WL 1909164, at *3 ("The specific ankle devices at issue are all the ankle devices that are distributed for use in patients beyond the 109 patients enrolled in an approved IDE clinical study and all ankle devices [the Appellees] describe as 'customs' or 'surgeon specials.'"). In other words, after the IDE clinical study became full in 2001, the Appellees continued to manufacture and distribute modified versions of the B-P Ankle, which, they contend, constitute custom devices exempt from the requirements of the FDCA. *See id.* at *5 ("Dr. Pappas testified that while the ankle devices at issue were similar to the standardized B-P Ankle that was being studied under the IDE, each had differences because each was designed for an individual patient, according to that patient's physiology and pathology.").

In 2001, Barbara Maulfair, an FDA investigator, inspected Endotec's New Jersey facility to collect information with respect to the IDE clinical study of the B-P Ankle. At trial, she testified that "Endotec's level of accountability was the

worst she had ever seen and violated FDA's regulations governing clinical trials." *Id.* at *3. As a result, the FDA issued a Form 483 to Endotec listing "seventeen observations which were significant deviations from the regulations." *Id*. Endotec's database identified 4,000 ankle units, but the IDE only included 109 patients. Her inspection revealed that Dr. Feldman (a clinical investigator under the approved IDE clinical study) had implanted 17 ankle devices into 17 new patients but failed to notify Endotec of these patients. In addition, Dr. Feldman had implanted 10 additional ankle devices as "surgeon specials" and Dr. Buechel (not a clinical investigator under the approved IDE clinical study) had implanted 218 ankle devices as "surgeon specials."

The 2001 inspection by Maulfair led the FDA to impose an Application Integrity Policy ("AIP") to Endotec on or about February 14, 2002 as a result of "system-wide failure by Endotec to ensure the integrity of data and that data submitted to FDA regarding this study [was] unreliable." *Id.* The AIP letter announced to Endotec that the FDA deferred action or review on any pending submissions or further submissions by Endotec "until questions regarding data integrity are resolved." On March 15, 2002, the FDA also issued a warning letter, informing Endotec that its shipment of B-P Ankles to Drs. Feldman and Buechel were not covered under the approved IDE clinical study and did not constitute

"custom devices."

Maulfair conducted two additional inspections of Endotec's New Jersey facility in 2002 and 2004. As a result of her second inspection, Maulfair determined that Endotec continued to ship ankle devices as custom devices. She observed that some of the ankle devices shipped to Dr. Buechel were marked with serial numbers "05," which referred to B-P Ankle components, and "95," which referred to custom device components. However, considering that the IDE had reached full enrollment, no B-P Ankle devices could be shipped under the IDE clinical study. As a result of her third inspection, Maulfair determined that Endotec continued to ship purported custom and standard B-P Ankle components.

Richard K. Vogel, an FDA investigator and a medical device specialist for the FDA, conducted two inspections of Endotec's Orlando facility. First, in August of 2004, Vogel sought "to collect documents regarding Endotec's shipment of ankle devies to two specific patients." *Id.* at *4. When he returned to finish the inspection in January of 2005, however, his investigation "changed to the collection of documentation of the manufacturing and shipment in interstate commerce of ankle devices manufactured between September 2004 and January 2005." *Id.* at *4. At the end of his investigation, Vogel explained to Pappas that the continued distribution of the B-P Ankle violated the law insofar as the IDE

clinical study had reached full enrollment and that the ankle devices were not custom devices. Second, in November of 2005, Vogel returned to the Orlando facility for a second inspection to investigate the distribution of unapproved devices and investigational devices outside the scope of the IDE for the B-P Ankle. Vogel observed that one shipment of a purported custom ankle device had been returned by the patient, sent back to Endotec's Orlando facility, repackaged and relabeled, and sent to another patient.

Dr. Pappas testified that, after Endotec received the 2002 warning letter, it limited the manufacture and distribution of ankle devices to custom designs. Dr. Buechel testified that while he was not a clinical investigator under the IDE clinical study for the B-P Ankle, he implanted B-P ankle devices as "surgeon specials before the 2002 warning letter from the FDA.[4] Dr. Buechel testified that he implanted only custom ankle devices after the letter. In April of 2007, however, he implanted a B-P Ankle device, but explained that it "must have been an emergency situation." *Id.* at *6.

2. *Knee device*

Endotec manufactures artificial knee devices with two types of designs: (1) the FlexGuide Knee Bearing with Anterior Stop, and (2) the Fenning Modular

[4] The phrase "surgeon specials" is one used by Endotec and, as far as we know, has no meaning under the FDCA or case law.

Bearing. Both devices were distributed to one surgeon, Dr. John Fenning.

3. *Jaw device*

The Hemi temporomandibular joint ("Hemi TMJ") is a partial jaw implant that Endotec distributed to one doctor for use in one particular patient not covered by an IDE clinical study as to a similar jaw device.[5] The patient who received the Hemi TMJ device was missing a large piece of bone in his jaw as a result of a tumor.

C. Procedural background

On August 23, 2007, the Government filed its "Amended Complaint for Permanent Injunction" against Endotec, Pappas, and Buechel in the United States District Court for the Middle District of Florida, seeking to enjoin the distribution of alleged adulterated and misbranded ankle, knee, and jaw implants in violation of 21 U.S.C. § 331(a), (k).[6] Specifically, the Government alleged that the specific

[5] Endotec has an FDA-approved IDE for a replacement TMJ device known as the Hoffman-Pappas temporomandibular joint ("H-P TMJ"). In 1997, the FDA approved an IDE clinical study for the H-P TMJ. The Government's case included the distribution of two H-P TMJ devices used for revision surgeries in patients enrolled in the IDE clinical study. The Government requested injunctive relief as to the two H-P TMJ devices, arguing that the revision surgeries went beyond the scope of the IDE protocol. The district court disagreed and found that the "two H-P TMJ devices used for revision surgeries did not constitute deviations from the study protocol, did not require prior approval from the FDA, and were exempt from [premarket approval] requirements." *Endotec*, 2008 WL 1909164, at *13. The H-P TMJ devices are not at issue here.

[6] The Government filed its original complaint approximately one year before its amended complaint, on or about August 28, 2006.

devices distributed by Endotec (1) constituted class III devices that did not qualify for any exemption from premarket approval, and, (2) as to the ankle device only, were subject to an IDE approved by the FDA but failed to comply with its requirements. As relief, the Government sought a permanent injunction and the disgorgement of profits. On September 4, 2007, the Appellees filed their "Amended Counter-Claim for Declaratory and Injunctive Relief and Damges," in which they sought (1) declaratory judgment of their rights; (2) a permanent injunction against the Government "from interfering with their manufacture of medical devices ordered by physicians or surgeons for use in their practice for their patients;" and (3) an order requiring the FDA to submit the B-P Ankle to a panel of independent experts for proper classification.[7] The Government moved for summary judgment, which the district court denied except with regard to the Appellees' request for referral of the B-P Ankle to an expert panel.

Beginning on March 18, 2008, the district court held a three-day bench trial. After the conclusion of the trial, the parties submitted written briefs and, on April 30, 2008, the district court issued its Order. *See Endotec*, 2008 WL 1909164, at *1. The district court enjoined the Appellees from manufacturing and distributing the knee device, but rejected the remainder of the Government's claims. First, as

[7] The Appellees filed their original counterclaim on or about May 7, 2007.

to the ankle devices, noting that the Government had not presented any evidence that the ankle devices were "potentially dangerous," the district court found that ankle devices met all of the requirements of a custom device exemption. *Id.* at *11-12. As to the IDE clinical study of the B-P Ankle, the district court also found that while "Endotec had faulty record-keeping, the Government has neither alleged that the B-P Ankle is unsafe or dangerous nor that [Endotec's] actions ha[s] caused harm to any patient." *Id.* at *12. Second, as to the knee devices, the district court found that Endotec had failed to identify any "special need" of Dr. Fenning as to each knee device. The Flex Guide Knee Bearing with Anterior Stop, moreover, "was implanted repeatedly in different patients." *Id.* Likewise, as to the Fenning Modular Bearing, Endotec presented no evidence that it manufactured said device to a particular patient's needs and Endotec had advertised said device for commercial distribution. As such, neither knee device qualified as a custom device. Third, as to the jaw device, the district court found that the Hemi TMJ met all of the requirements of a custom device. The district court also denied the Government's request for a disgorgement of profits and ordered each party to bear its own costs and attorney's fees.

On May 1, 2008, the district court entered judgment in favor of the Appellees. On June 26, 2008, the Government filed a Notice of Appeal as to the

district court's conclusions related to the ankle and jaw devices. On July 10, 2008, the Appellees filed a Notice of Appeal as to the district court's conclusions related to the knee device.

II.

"We review the ultimate decision of whether to grant a preliminary injunction for abuse of discretion, but we review *de novo* determinations of law made by the district court en route." *Owner-Operator Independent Drivers Ass'n, Inc. v. Landstar System, Inc.*, 541 F.3d 1278, 1293 (11th Cir. 2008) (citing *Teper v. Miller*, 82 F.3d 989, 993 (11th Cir. 1996)). Questions of law subject to *de novo* review include questions of statutory and regulatory construction. *See Lippert v. Community Bank, Inc.*, 438 F.3d 1275, 1278 (11th Cir. 2006) (reviewing questions of statutory construction *de novo*); *United States v. Pistone*, 177 F.3d 957, 958 (11th Cir. 1999) (per curiam) ("The interpretation of a statute is a question of law subject to *de novo* review."). However, we review "findings of fact upon which the decision to grant equitable relief was made under the clearly erroneous standard." *Atlanta Journal and Constitution v. City of Atlanta Dept. of Aviation*, 442 F.3d 1283, 1287 (11th Cir. 2006).

In considering the Government's request for a permanent injunction under the FDCA, the district court did not consider the traditional equitable criteria for

injunctive relief.[8] *See Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc) (per curiam) ("A district court may grant injunctive relief only if the moving party shows that: (1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest."); *KH Outdoor, LLC v. City of Trussville*, 458 F.3d 1261, 1268 (11th Cir. 2006) ("For a permanent injunction, the standard is essentially the same [as that for a preliminary injunction], except that the movant must establish actual success on the merits, as opposed to a likelihood of success." (citing *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 546 n.12 (1987))). On appeal, neither party argues that the district court erred in doing so.

Rather, the Government argues that the district court erred in finding that (1) ankle and jaw devices constitute a custom device and (2) that the Appellees did not violate the IDE clinical study of the B-P Ankle. Likewise, the Appellees argue in their cross-appeal that the district court erred in finding that the knee device did not constitute a custom device. In doing so, both parties challenge the district court's findings as to the applicability of an exemption to a statutory scheme.

[8] The district court did not specifically indicate the standard of review that it applied for a permanent injunction under the FDCA.

Significantly, the Appellees in their cross-appeal do *not* argue that the Government failed to meet *its* burden of proof to demonstrate the propriety of a permanent injunction as to the knee device, or the ankle and jaw devices. As such, we need not speculate as to the proper standard of review for injunctive relief pursuant to section 332 of the FDCA and we decline to consider whether the Government met *its* burden.[9] Rather, as to both the Government's appeal and the Appellees' cross-

[9] We have not yet had the occasion to address explicitly the proper standard of review for injunctive relief under the FDCA. Fifth Circuit precedent, however, suggests that a moving party need prove only a violation of the statute at issue. In *United States v. Hoxsey Cancer Clinic*, 198 F.2d 273 (5th Cir. 1952), the Fifth Circuit considered a claim for injunctive relief sought by the Government under section 332 of the FDCA "to prevent the Hoxsey Cancer Clinic, and Harry M. Hoxsey, from introducing or delivering for introduction into interstate commerce bottles of brownish-black, and pink, colored liquids intended for use in the treatment and cure of cancer in man." *Id.* at 274. That case concerned a booklet that accompanied cancer drugs and contained general and specific statements regarding the treatment, mitigation, and cure of cancer. The Fifth Circuit reversed the district court's denial of injunctive relief. In doing so, it did not apply the traditional equitable criteria. Rather, considering an injunction as to the Government's claims of false and misleading statements, the Fifth Circuit limited its analysis to the language of the statute: "The statute seeks to prevent labeling which is false or misleading in any particular. Proof that such representation in the case of at least nine of the persons represented as cured was false establishes the falsity of such representation in a most significant particular." *Id.* at 281. As such, the Fifth Circuit found an injunction appropriate pursuant to section 332 of the FDCA where the Government demonstrated a violation of the statutory provisions at issue without any mention of the traditional equitable criteria. *See also United States v. Vital Health Products, Ltd.*, 786 F. Supp. 761, 770 (E.D. Wis. 1992) (providing that, to obtain injunctive relief under the FDCA, "[t]he government need only show that the defendant has violated the Act and that there is a reasonable chance of recurring violations"); *United States v. 22 Rectangular or Cylindrical Finished Devices, More or Less, * * * the Ster-O-Lizer MD-200 * * *, Halogenic Products Co.*, 714 F. Supp. 1159, 1167 (D. Utah 1989) ("Provisions such as section 332(a), which restrain persons from violating laws of the United States, are satisfied where the statutory conditions for relief are met; no additional showing must be made for an injunction to issue."). *But see Klay v. United Healthgroup, Inc.*, 376 F.3d 1092, 1099 (11th Cir. 2004) (providing that, as a general matter with respect to the proper standard of review for a statutorily-authorized injunction, "no overarching general principles are readily apparent").

In the same way, the Second and Ninth Circuits have applied modified standards to a request for injunctive relief pursuant to the FDCA. In *United States v. Diapulse Corp. of*

appeal, the dispute concerns whether the medical devices fall under an exception to premarket approval, specifically the custom device exemption as to the ankle, knee, and jaw devices and the IDE exemption as to the ankle device. As such, in line with the district court's analysis as well as the parties' briefs, we limit our discussion to whether the respective medical devices meet the statutory criteria of the exemptions *only*. The Appellees bear that burden.[10] *See United States v. First City Nat. Bank of Houston*, 386 U.S. 361, 366 (1967) (providing that the "general rule" places the burden "where one claims the benefits of an exception to the prohibition of a statute"); *Fed. Trade Comm'n v. Morton Salt Co.*, 334 U.S. 37, 44-45 (1948) (providing that "the general rule of statutory construction that the burden of proving justification or exemption under a special exception to the prohibitions of a statute generally rests on one who claims its benefits"); *United States v. An Article of Drug . . . "Bentex Ulcerine,"* 469 F.2d 875, 878 (5th Cir.

America, 457 F.2d 25 (2d Cir. 1972), a pre-MDA case, the Second Circuit explained that "[t]he passage of the [FDCA] is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained." *Id.* at 28. Hence, "[n]o specific or immediate showing of the precise way in which violation of the law will result in public harm is required." *Id.* The Second Circuit did consider "the likelihood of continuing violation or recommencement of the offensive behavior, if it has ceased during the pendency of the litigation." *Id.* at 28-29. Likewise, in *United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172 (9th Cir. 1987), the Ninth Circuit applied a watered-down version of the traditional equitable criteria, presuming "that the government would suffer irreparable injury from a denial of its motion" and requiring only "some chance of probable success on the merits." *Id.* at 175-76. The Ninth Circuit, however, still considered the public interest as well as the likelihood of recurring violations. *Id.* at 176.

[10] The Appellees do not argue to the contrary.

1972) (per curiam), *cert. denied*, 412 U.S. 938 (1973) (providing that the party claiming the protection of the "Grandfather Clause" exemption to the FDCA's premarket approval requirement as to a "new drug" "must prove every essential fact necessary for invocation of the exemption"); *United States v. Kanasco, Ltd.*, 123 F.3d 209, 211 (4th Cir. 1997) (providing that "[t]he burden of pleading and proving the applicability of [the export exemption to the FDCA's requirement of "current good manufacturing practice"] is on . . . the party that seeks the benefit of the exemption"); *United States v. An Article of Device*, 731 F.2d 1253, 1262 (7th Cir. 1984) (providing that, in an action brought by the government for a declaration that a device was "misbranded" under the FDCA, the party claiming the exemption who "appear[s] to be in the better position to come forward with evidence that the [device] works safely and effectively" bears the burden of proving its application). We construe statutory exemptions strictly against the party who invokes its benefit. *See An Article of Drug . . . "Bentex Ulcerine,"* 469 F.2d at 878 (providing that the "Grandfather Clause" exemption to the FDCA's requirement of premarket approval of a "new drug" "is to be strictly construed against the one who invokes its protection"). Strict construction of an exemption to a statutory scheme is all-the-more necessary where the statute at issue addresses public health and safety, such as the MDA and FDCA. *See United States v. Articles of Drug Consisting of*

Following: 5,906 Boxes, 745 F.2d 105, 113 (1st Cir. 1984) (providing that "as an exemption to a comprehensive regulatory statute concerned with public safety [i.e., the FDCA], the grandfather clause is to be strictly construed"); *USV Pharm. Corp. v. Richardson*, 461 F.2d 223, 227-28 (4th Cir. 1972) (addressing the "grandfather clause" exemption to the FDCA and providing "that statutory exemptions, particularly as applied to statutes concerned with public health and safety, are to be strictly and narrowly construed"). With the proper standard of review in mind, and the scope of our review defined, we turn to the medical devices at issue.

III.

The Government challenges the district court's order as to the ankle and jaw devices insofar as it found both devices fall under the custom device exemption. The Government also challenges the district court's finding that the Appellees did not exceed the scope of the IDE clinical study of the B-P Ankle. The Appellees challenge the district court's order as to the knee device insofar as it found that said device did not fall under the custom device exemption. We will address each medical device in turn.

A. Ankle device

The Government asserted two distinct yet related claims as to the manufacture and distribution of the ankle device. First, the Government contended

that the Appellees violated 21 U.S.C. § 331(a), which prohibits the introduction into interstate commerce of any adulterated device, and 21 U.S.C. § 331(k), which prohibits causing a device to become adulterated while being held for sale after shipment in interstate commerce. The Appellees defended that claim by asserting protection under the custom device exemption. Second, the Government contended that the Appellees failed to comply with the FDA's IDE regulations in their clinical study of the B-P Ankle device in violation of 21 U.S.C. §§ 351(i) and 331(q)(1). The Appellees asserted that they implemented remedial measures to cure any past problems. We will address first the custom device exemption and then the IDE exemption.

1. Custom device exemption

The MDA exempts "custom devices" from premarket approval. A custom device is one that

> necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 360e of this title if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device--
> (A)(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

> (ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and
> (B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

21 U.S.C. § 360j(b). Stated differently, 21 C.F.R. § 812.3 tracks the statutory language for the most part but breaks down the custom device requirements into a list format:

> Custom device means a device that:
> (1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
> (2) Is not generally available to, or generally used by, other physicians or dentists;
> (3) Is not generally available in finished form for purchase or for dispensing upon prescription;
> (4) Is not offered for commercial distribution through labeling or advertising; *and*
> (5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

21 C.F.R. § 812.3(b) (emphasis added).

As a threshold matter, we note that the district court considered issues outside the scope of the definition of a custom device. In particular, the district

court noted that "the Government did not present any evidence to indicate that the ankle devices were potentially dangerous." *Endotec*, 2008 WL 1909164, at *11; *see id.* (addressing all the medical devices in general and providing that "[i]t is noteworthy that throughout the duration of these proceedings, the FDA has not alleged that Defendants have harmed any individual by manufacturing or distributing medical devices and has not alleged that any of Defendants' devices are dangerous or that their use poses any risk"). In support, the district court relied upon *Contact Lens Manufacturers Association v. Food & Drug Administration*, 766 F.2d 592 (D.C. Cir. 1985), in which the Contact Lens Manufacturers Association ("CLMA") filed suit to challenge the FDA's withdrawal of its own proposal to transfer certain contact lenses from Class III to Class I. *See id.* at 594. The district court's reliance on *Contact Lens* for the proposition that the party seeking injunctive relief under the FDCA must demonstrate dangerousness or actual harm with respect to a medical device is misplaced for two reasons. First, by requiring the Government to show dangerousness or actual harm, the district court effectively shifted the burden of persuasion as to the custom device exemption from the Appellees to the Government. And second, notwithstanding the former, the custom device definition does not require any showing of dangerousness or actual harm from the Government. In noting that the

Government "did not present any evidence to indicate that the ankle devices were potentially dangerous," *Endotec*, 2008 WL 1909164, at *11, the district court cited a passage in *Contact Lenses*, in which the FDA expressed concern with regard to the "safety and effectiveness" of soft contact lenses. *See Contact Lenses*, 766 F.2d at 595. That passage, however, related to the D.C. Circuit's discussion of the reclassification of the contact lenses. *See id*. The D.C. Circuit did not discuss or even make any mention of dangerousness or actual harm with respect to the custom device exemption but instead limited its analysis thereto to the five prongs of the custom device definition. *See id.* at 598-99. *Contact Lenses*, therefore, does not lend support to any requirement that the party not claiming protection of the custom device exemption must demonstrate potential dangerousness or actual harm caused by the disputed medical device.

The district court concluded that the ankle devices distributed by Endotec beyond the scope of the IDE clinical study constituted custom devices and hence were exempt from premarket approval. The Government argues that the district court abused its discretion in concluding that the ankle devices qualified as custom devices. Specifically, the Government asserts that the ankle devices fail each prong of the definition of a custom device. We conclude that the district court erred with respect to one prong of the custom device definition and, because a

device must meet all five prongs of the custom device definition, we decline to address the remainder.

A custom device is a device that "[i]s not offered for commercial distribution through labeling or advertising." 21 C.F.R. § 812.3(b)(4); 21 U.S.C. § 360j(b) (providing that a custom device "is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution"). The district court found that "[the Appellees] did not offer the custom ankle devices for commercial distribution through advertising or labeling."[11] *Endotec*, 2008 WL 1909164, at *12. In doing so, the district court addressed only the advertisements on Endotec's website and Dr. Buechel's private practice website. *See id*. ("Any references to ankle devices on Endotec's website or on Dr. Buechel's private practice website refer to the B-P Ankle, and not the unique ankle devices at issue in this case."). The district court, however, failed to

[11] While the district court found that Endotec did not offer the custom ankle devices for commercial distribution through advertising or labeling, it included language that appeared to contradict its own conclusion. After finding that Endotec advertised only the B-P Ankle, the district court warned Endotec regarding its future advertising and marketing, seemingly conceding that it had unlawfully advertised or marketed the custom ankle devices: "The Court cautions . . . that Defendants must scrutinize their website and other marketing materials carefully to avoid the unlawful advertising or marketing these devices." *Endotec*, 2008 WL 1909164, at *12. The district court then went a step further, enjoining Endotec "from advertising the B-P Ankle or any custom ankle devices through websites, in professional journals, at professional conferences, or through any other means and the ankle devices may be used by prescription only." *Id.* at *14. Therefore, the district court warned the Appellees as to future advertisements and even enjoined them from advertising the B-P Ankle or any custom ankle device yet it found no violation of that prong.

address another advertisement raised by the Government. Based on our review of that advertisement as well as the advertisement on Dr. Buechel's website, we conclude that the Appellees advertised the purported custom ankle devices for commercial distribution in violation of the custom device definition.

First, the Appellees advertised the custom devices through a July/August 2006 edition of Orthopaedic News, containing an advertisement for "Endotec customs."[12] The subsequent text refers to, *inter alia*, custom ankle devices as Endotec's "speciality." On its face, the advertisement offers custom ankle devices by Endotec for commercial distribution. By its own language, this advertisement cannot be attributed to the B-P Ankle device as it explicitly refers to "Endotec customs," which we read as a reference to custom ankle devices, not the B-P Ankle. Such a reference constitutes an impermissible advertisement of a custom device. Endotec offers no explanation to the contrary, except to assert that the Federal Register allows them to advertise custom devices of a "generic type." However, even if we were to endorse a "generic type" exception to the prohibition against advertisement for commercial distribution, this advertisement is anything but generic. On the contrary, the advertisement specifically refers to Endotec custom ankle devices.

[12] The district court made no mention of this advertisement.

Second, the district court found that any advertisement on Dr. Buechel's medical practice website (South Mountain Orthopaedic Associates) referred to the B-P Ankle, not the custom ankle devices. *See Endotec*, 2008 WL 1909164, at *12. We do not quarrel with the district court's factual finding that the website literally "refer[red]" to the B-P Ankle. The face of the advertisement on the website speaks for itself. *See* R., Ex. 11.[13] The Government agrees. *See* Br. For Appellant at 36. However, we disagree with the district court's conclusion that, because the website referred to the B-P Ankle by name only, the Appellees did not violate the commercial distribution prong of the custom device definition because, as the district court also found, Dr. Buechel's reference to the B-P Ankle on his website necessarily included the purported custom ankle devices manufactured and distributed by Endotec.

The district court found that "Dr. Buechel implanted B-P Ankles *as surgeon specials* until 2002 when [the] FDA issued its warning letter to Endotec." *Endotec*, 2008 WL 1909164, at *6 (emphasis added). Specifically, the district court found that "Dr. Buechel . . . had implanted 218 ankle devices as 'surgeon specials.'" *Id.* at *3. According to the Appellees, "surgeon specials" is a term used by Endotec to refer to "a device made to a surgeons [sic] specifications, to be used only in that

[13] The advertisement is dated February 26, 2007.

surgeons [sic] practice and not for general distribution." Appellees' Resp. Br. And Principal Br. at 12 (quotation marks and citation omitted). The district court found that "surgeon specials," as that phrase is used by the Appellees, and the purported custom ankle devices manufactured and distributed by the Appellees, are one and the same. *See Endotec*, 2008 WL 1909164, at *3 ("The specific ankle devices at issue are all the ankle devices that are distributed for use in patients beyond the 109 patients enrolled in an approved IDE clinical study *and all ankle devices [the Appellees] describe as 'customs' or 'surgeon specials*.") (emphasis added). Therefore, according to the district court's finding that Dr. Buechel implanted B-P Ankles as "surgeon specials," the advertisement of the B-P Ankle on Dr. Buechel's website encompassed the advertisement of surgeon specials, or the purported custom ankle devices.[14] Our conclusion is further bolstered by the fact that Dr. Buechel was not an approved investigator under the IDE clinical study of the B-P Ankle and, as such, he could not even implant the B-P Ankle. *See id.* at *6 ("Dr. Buechel admitted that he is not a clinical investigator for the B-P Ankle and that means he cannot implant B-P Ankles pursuant to the approved IDE."). Such an advertisement of a purported custom ankle device violates the commercial

[14] Ms. Maulfair testified that Endotec's "surgeon specials" and the purported custom ankle devices manufactured and distributed by Endotec contain "the same three components," specifically the tibial, the talar, and the mobile bearing. *See* Tr. of R., V. 7, 15:3-7 (Deposition of Barbara J. Maulfair).

distribution prong of the custom device definition.

In defense of the advertisement, the Appellees do not echo the district court's finding that the advertisement referred only to the B-P Ankle. Rather, they provide another explanation: a disclaimer on the website advising that the B-P Ankle is only available through the "compassionate use" program cures any violation of the prohibition against the commercial distribution of custom ankle devices.[15] We disagree. The Appellees fail to direct us to any statute, rule, or case that allows for a disclaimer exception to the commercial distribution prong and they bear the burden to demonstrate that their device constitutes a custom device. Moreover, we refuse to allow a disclaimer to shield the Appellees from what otherwise constitutes blatant advertisement of their purported custom ankle devices. Such a rule would render the commercial distribution prong of the custom device definition ineffective and meaningless.

Given the nature of the custom device definition, either of the advertisements of the custom ankle devices, *standing alone*, removes the ankle device from the protection of the custom device exemption. Accordingly, we find

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[15] The compassionate use exception allows a drug company to distribute an unapproved drug if: (1) the drug is for a serious or life-threatening disease, (2) there is no good alternative, (3) the drug is currently under investigation in a clinical trial, and (4) the sponsor is actively pursuing marketing approval. 21 C.F.R. § 312.34. However, even if the drug meets these criteria, the FDA may still deny the compassionate use if there is insufficient evidence of the drug's safety. *Id.*

that the Appellees have failed to carry their burden as to the commercial distribution prong.

2. *IDE*

The Government contends that the district court erred in refusing to enjoin the Appellees from manufacturing and distributing the B-P Ankle until they fully complied with the IDE regulations. Specifically, according to the Government, the evidence demonstrates that the Appellees' repeatedly violated the requirements of the IDE clinical study, including Dr. Feldman's implantation of 10 ankle devices beyond the scope of the IDE clinical study and Dr. Buechel's implantation of 217 ankle devices, even though he was not an investigator under the IDE clinical study. The Appellees respond that, after receipt of the AIP and March 2002 warning letter, it took remedial measures to obtain compliance with the IDE clinical study on the B-P Ankle and the FDA lifted the AIP.

The FDCA provides for an "investigational device exemption" in 21 U.S.C. § 360j(g) to remove what would otherwise be a "catch-22:" a Class III device may not be shipped in interstate commerce until it has been approved by the FDA, but, to obtain the test data needed for approval, a device has to be shipped in interstate commerce to physicians who will test the device in patients under controlled circumstances. Accordingly, the IDE exemption lifts the prohibition on shipment

in interstate commerce of an unapproved Class III device and permits the investigational use of unapproved devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices pursuant to protocol imposed by the FDA. 21 U.S.C. § 360j(g). To obtain an IDE exemption, a manufacturer must satisfy the requirements of 21 U.S.C. § 360j(g) as well as 21 C.F.R. § 812.20.

The district court's own findings of fact intimate that the Appellees manufactured and distributed the B-P Ankle device in violation of the IDE clinical study:

> Dr. Buechel admitted that he is not a clinical investigator for the B-P Ankle and that means he cannot implant B-P Ankles pursuant to the approved IDE. However, Dr. Buechel implanted B-P Ankles as surgeon specials until 2002 when FDA issued its warning letter to Endotec. Since 2002, Dr. Buechel has only implanted what he describes as custom ankle devices. Dr. Buechel admitted that in April 2007, he implanted an ankle device in which all the component numbers began with '05,' indicating that it was the standard B-P Ankle. Dr. Buechel offered that the particular situation must have been an emergency situation. In other situations, Dr. Buechel used components that had been originally manufactured for another patient because it offered the patient the best fit.

Endotec, 2008 WL 1909164, at *6. In other words, Dr. Buechel admitted that he implanted the B-P Ankle device on an undetermined number of occasions before the March 2002 warning letter. This admission demonstrates a violation of the

IDE clinical study requirements in that Dr. Buechel was not an approved investigator under the B-P Ankle IDE clinical study. The Appellees nevertheless argue that they have implemented "remedial measures" since the March 2002 warning letter. This argument fails to convince us for two reasons. First, the Appellees do not identify specifically what "remedial measures."[16] And second, even if they had enacted "remedial measures," such subsequent action does not somehow ameliorate their past violations of the B-P Ankle IDE clinical study. In addition, Dr. Buechel's admission that he implanted a B-P Ankle device on one occasion after the March 2002 warning letter belies their "remedial measures" argument insofar as such measures proved ineffective on at least that one occasion.

The district court's decision not to enjoin the Appellees' manufacture and distribution of the B-P Ankle relied upon findings irrelevant to whether they complied with the IDE clinical study of the B-P Ankle. The district court determined that Endotec had not violated 21 U.S.C. §§ 351(i) and 331(q)(1),[17] finding that, "since the March 2002 warning letter, [Endotec] ha[s] been in

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[16] In all likelihood, "remedial measures" refer to the Appellees' contention that, after the March 2002 warning letter, they manufactured and distributed only custom ankle devices, or "surgeon specials." We have already rejected that argument.

[17] Section 331, entitled "Prohibited acts," prohibits the failure or refusal to comply with the IDE requirements under section 360j(g), *see* 21 U.S.C. § 331(q)(1), and section 351, entitled "Adulterated drugs and devices," provides that failure to comply with requirements under which a device was exempted for investigational use renders the device adulterated, *see* 21 U.S.C. § 351(I).

substantial compliance regarding the B-P Ankle." *Endotec*, 2008 WL 1909164, at *11. Despite the Appellees' "faulty record-keeping," the district court appeared to base its conclusion on two points: (1) the Government had alleged neither that the B-P Ankle was unsafe or dangerous nor that the Appellees' actions caused any harm to any patient; and (2) the "FDA's stringent regulations strict interpretation of procedural requirements are resulting in technological innovation being stymied, rather than advanced." *Id.* at 12. Neither consideration, however, represents a valid reason in support of its finding that the Appellees did not violate the requirements of the IDE clinical study of the B-P Ankle.

First, similarly to the custom device exemption, neither the statute providing for the IDE exemption nor the applicable regulations require the Government to allege, much less to prove, that a device (alleged to exceed the scope of an IDE) is "unsafe" or "dangerous." The district court cited no authority for the new "dangerous" requirement and the Appellees fail to cite to any binding or persuasive case law in support thereof.[18] We find the Sixth Circuit instructive here:

> It is not the government's burden to prove that a product is not safe and effective. FDCA regulations exist to allow the public to assume that marketed devices have received the imprimatur of FDA approval. To circumvent the law by marketing illegally without

[18] At oral argument, counsel for the Appellees even agreed that dangerousness was not a proper consideration.

> approval is to deceive the public both as purchasers and users of the device.

United States v. Universal Mgmt. Services, Inc., Corp., 191 F.3d 750, 763 (6th Cir. 1999). We decline to impose a dangerousness requirement as to the IDE exemption. By punishing the Government for failing to prove the dangerousness of the ankle device, the district court held the Government to a standard that it need not meet.

Second, the district court's commentary that the FDA's interpretation of the MDA stymies, rather than advances, innovation fails to justify its ruling. *See Endotec*, 2008 WL 1909164, at *12. Congress crafted the IDE exemption to advance innovation: "The purpose of [the IDE exemption] is to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose." 21 U.S.C. § 360j(g)(1); 21 C.F.R. § 812.1(a). "However, fostering innovation does not require the elimination of all burdens on medical device manufacturers. . . ." *Webster v. Pacesetter, Inc.*, 171 F. Supp. 2d 1, 14 (D.D.C. 2001). The district court noted that "the evidence presented at trial showed that the B-P Ankle provided greater benefits to patients than the alternatives available in the United States." *Endotec*, 2008 WL 1909164, at *12.

In this statement, the district court exceeded the proper scope of its inquiry by addressing the medical benefits of the B-P Ankle device versus other alternative ankle devices as opposed to confining its inquiry to the alleged violations of sections 351(i) and 331(q)(1) by the manufacture and distribution of the B-P Ankle beyond the scope of the IDE clinical study. It is not within the province of the district court (or, this Court, for that matter) to weigh the medical pros and cons of a certain medical device – that is best left to the FDA.

Accordingly, we conclude that the district court employed faulty reasoning in finding that the Appellees had not violated sections 351(i) and 331(q)(1). Considering that the district court is better acquainted with the evidence and the parties, we remand to give the district court another opportunity: (1) to consider whether the Appellees violated sections 351(i) and 331(q)(1) through the manufacture and distribution of the B-P Ankle outside the IDE clinical study based on the record evidence; (2) to consider, in the first instance, whether this issue as to the IDE clinical study is now moot in light of the fact that the FDA has lifted the AIP; and (3) to resolve any other issues related to the IDE clinical study that the district court deems appropriate.

B. Knee device

On cross-appeal, the Appellees argue that the district court abused its

discretion in determining that the knee device did not constitute a custom device, specifically as to the "special needs" clause of the custom device exemption that falls under the last prong of the definition. The Government responds arguing that the district court committed no error.

The district court concluded that the two knee devices did not qualify as custom devices. As to the Flex Guide Knee Bearing with Anterior Stop, the district court found that the Appellees did not identify any "special need" of Dr. Fenning and "the same bearing was implanted repeatedly in different patients." *Endotec*, 2008 WL 1909164, at *12. As to the Fenning Modular Bearing, the district court found that the Appellees again did not identify any "special need" of Dr. Fenning that required the use of the device, and "Dr. Pappas admitted that Endotec advertised the Fenning Modular Bearing on a flyer which was posted on Endotec's website." *Id.* at *13.

In support of its argument that the knee devices constitute custom devices, the Appellees invoked the "special needs" clause of the custom device exemption. *See* 21 U.S.C. § 360j(b)(A)(ii) (providing that a custom device "is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated)"); 21 C.F.R. § 812.3(b)(5)

(providing that a custom device "is intended to meet the special needs of the physician or dentist in the course of professional practice"). On appeal, the Appellees fail to demonstrate that the district court abused its discretion. As to either knee device, the Appellees fail to identify a "special need" of Dr. Fenning; rather, the Appellees merely argue that the special needs provision "permits a physician to use the same medical [sic] to treat more than one patient in the course of his professional practice." Even if taken as true, the Appellees' argument still fails to address the "special need" requirement. As to the Fenning Modular Bearing, moreover, the district court concluded that Endotec advertised it in a flyer posted on Endotec's website in violation of the commercial distribution prong. Endotec attempts to explain the flyer advertisement as "test[ing] the waters" and, when the device garnered no interest, it pulled the flyer. This argument lacks merit because there is no "test[ing] the waters" exception to the commercial distribution prong of the custom device definition.[19] The Government nonetheless contends

[19] In support of their "test[ing] the waters" theory, the Appellees rely upon 21 C.F.R. § 812.2(c), which lists exemptions from the IDE regulations including the custom device exemption. In particular, the Appellees point to the "consumer preference testing" provision, which exempts "[a] device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk." 21 C.F.R. § 812.2(c)(4). The Appellees' argument is misguided, however, insofar as they attempt to use the "consumer preference testing" exemption to define the scope of one of the prongs of the custom device exemption. Further, the Appellees fail to show that any "consumer preference testing" did not "put subjects at risk." *Id.*

that the flyer advertisement remains posted on Endotec's website.

Accordingly, Endotec has failed to show that the district court abused its discretion as to the knee device.

C. Jaw device

The Government argues that the district court abused its discretion in determining that the Hemi TMJ device constituted a custom device because the Appellees failed to show that it was "not generally available to, or generally used by, other physicians or dentists."[20] In support, the Government points to an FDA regulation addressing this type of implant.[21] The Appellees respond that Dr. Pappas testified that the device available did not meet the patient's specific needs because he had lost a bone in his jaw.

The district court found that the Hemi TMJ device used for that particular patient "was not generally available to or used by other physicians." *Endotec*, 2008 WL 1909164, at *14. The district court explained that the Appellees specifically designed the Hemi TMJ to account for a particular patient's bone loss as a result of a tumor. Here, the Government essentially asserts that the Appellees

[20] The Government does not address any other prong under the custom device definition as to the Hemi TMJ and, therefore, neither do we.

[21] Section 872.3950 identifies a "glenoid fossa prosthesis" as a Class III device "that is intended to be implanted in the temporomandibular joint to augment a glenoid fossa or to provide an articulation surface for the head of a mandibular condyle." 21 C.F.R. § 872.3950(a)-(b).

needed to present *more* evidence before the district court to demonstrate why the available jaw implant (under 21 C.F.R. § 872.3950) did not fit that patient: "But Dr. Pappas did not address the features of the commercially available product and demonstrate that it was unsuitable for this patient."

The Government's argument amounts to one of degree. While Dr. Pappas testified that the commercially available device did not meet the patient's needs because of his tumor-related bone loss and the Government concedes that the Hemi TMJ included special features designed for the particular patient, the Government merely demands more evidence. The custom device definition requires that the device at issue – the Hemi TMJ device – "[i]s not generally available to, or generally used by, other physicians or dentists." The district court concluded that the Appellees met their burden and the Government has failed to show that it abused its discretion as to the Hemi TMJ.

IV.

In summary, we find no reversible error as to the knee and jaw device and we affirm the district court's entry of a permanent injunction as to the same. As to the ankle device, however, we find that the district court abused its discretion in denying the Government's request for a permanent injunction. Because Endotec has not carried its burden to demonstrate that the ankle device falls under the

custom device exemption, we reverse the district court's ruling as to the ankle device and remand with instructions for the district court to enter a permanent injunction as to the ankle device in favor of the Government.[22] As to the regulatory IDE violation, we remand to the district court for consideration in light of this Opinion.

AFFIRMED in part as to the permanent injunction for the knee and jaw devices, and REVERSED in part as to the ankle device with instructions to enter a permanent injunction, and REMANDED to the district court for further proceedings consistent with this Opinion.

[22] We leave it to the district court to craft the proper permanent injunction.