Office of Chief Counsel
Internal Revenue Service
Memorandum

Number: **201520006**
Release Date: 5/15/2015

CC:PSI:07:AFDunlap
POSTN-140673-14

UILC: 4191.00-00

date: January 28, 2015

to: Kellie McCann
Program Manager, Excise Tax Program

from: Stephanie Bland
Branch Chief, CC:PSI:7

---

subject: Applicability of section 4191(b)(2)(D) Retail Exemption

This responds to your request for taxpayer specific legal advice regarding the application of the retail exemption in section 4191(b)(2)(D) of the Internal Revenue Code (Code). This advice may not be used or cited as precedent.

LEGEND

Medical Device Company	=
medical device	=
$A	=
$B	=
$C	=
$D	=

ISSUE

Whether Medical Device Company's medical device of falls within the retail exemption set forth in section 4191(b)(2)(D) of the Code and section 48.4191-2(b)(2) of the Treasury Regulations (Regulations) such that the medical device is not subject to tax under section 4191(a).

CONCLUSION

The medical device falls within the retail exemption of section 4191(b)(2)(D) of the Code because it is a device of a type that is generally purchased by the general public at retail for individual use.

FACTS

Medical Device Company manufactures the medical device, a . The medical device is a

.

For purposes of this advice, the term "medical device" includes only the , and the . It does not include anything not listed below. Both the and the are listed as devices with the FDA under section 201(h) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, pursuant to FDA requirements. Neither the nor the are Class III devices under the FDA system of classification.

The medical device includes:

Medical Device Company does not enter any agreements directly with patients; all of its dealings with respect to the medical device are with the doctor (i.e.,). A doctor develops a customized treatment plan for the patient that is considered a prescription to Medical Device Company and is Medical Device Company's final authorization to manufacture the . Upon authorization from a doctor, Medical Device Company will develop a .

Medical Device Company sells the medical device directly to doctors. The price a doctor pays to Medical Device Company generally ranges from $A to $B for and from $C to $D for . The price a doctor pays for the medical device (and the price the patient ultimately pays to the doctor) varies depending on the chosen treatment plan.

LAW

Section 4191(a) imposes a 2.3 percent tax on the sale of a taxable medical device by its manufacturer, producer, or importer.

Section 4191(b)(1) provides that "taxable medical device" means a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) that is intended for humans.

Section 4191(b)(2) provides that "taxable medical device" shall not include eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.

Section 48.4191-2(b)(2) provides that the term "taxable medical device" does not include any device of a type that is generally purchased by the general public at retail for individual use. A device will be considered to be of a type that is generally purchased by the general public at retail for individual use if it is regularly available for purchase and use by individual consumers who are not medical professionals, and if the

design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional. Whether a device is of a type described in the preceding sentence is evaluated based on all the relevant facts and circumstances. This section further provides that the determination of whether a device is of a type that qualifies for the retail exemption is made based on the overall balance of factors relevant to the particular type of device. The fact that a device is of a type that requires a prescription is not a factor in the determination of whether or not the device falls under the retail exemption.

Section 48.4191-2(b)(2)(i) provides that the following factors are relevant in determining whether a device is of a type that is regularly available for purchase and use by individual consumers who are not medical professionals:

(A) Whether consumers who are not medical professionals can purchase the device in person, over the telephone, or over the Internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell devices (for example, specialty medical stores, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers and similar vendors);
(B) Whether consumers who are not medical professionals can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional; and
(C) Whether the device is classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medicine Devices).

Section 48.4191-2(b)(2)(ii) provides that the following factors are relevant in determining whether a device is designed primarily for use in a medical institution or office or by a medical professional:

(A) Whether the device generally must be implanted, inserted, operated, or otherwise administered by a medical professional;
(B) Whether the cost to acquire, maintain, and/or use the device requires a large initial investment and/or ongoing expenditure that is not affordable for the average individual consumer;
(C) Whether the device is a Class III device under the FDA system of classification;
(D) Whether the device is classified by the FDA under-
    1. 21 CFR part 862(Clinical Chemistry and Clinical Toxicology Devices), 21 CFR part 864 (Hematology and Pathology Devices), 21 CFR part 866 (Immunology and Microbiology Devices), 21 CFR part 868 (Anesthesiology Devices), 21 CFR part 870 (Cardiovascular Devices), 21 CFR part 874 (Ear, Nose, and Throat Devices), 21 CFR part 876 (Gastroenterology-Urology Devices), 21 CFR part 878 (General and Plastic Surgery Devices), 21 CFR part 882 (Neurological Devices), 21

CFR part 886 (Ophthalmic Devices), 21 CFR part 888 (Orthopedic Devices), or 21 CFR part 892 (Radiology Devices);
2. Subpart B, Subpart D, or Subpart E of 21 CFR part 872 (Dental Devices);
3. Subpart B, Subpart C, Subpart D, Subpart E, or Subpart G of 21 CFR part 884 (Obstetrical and Gynecological Devices); or
4. Subpart B of 21 CFR part 890 (Physical Medicine Devices); and

(E) Whether the device qualifies as durable medical equipment, prosthetics, orthotics, and supplies for which payment is available exclusively on a rental basis under the Medicare Part B payment rules, and is an "item requiring frequent and substantial servicing" as defined in 42 CFR 414.222.

Section 48.4191-2(b)(2)(iii) is a safe harbor provision that identifies devices that will be considered to be of a type generally purchased by the general public at retail for individual use. The safe harbor includes (i) devices that are identified in the FDA's IVD Home Use Lab Tests (Over-the-Counter Tests) database; (ii) devices described as "OTC" or "over the counter" devices in the relevant FDA classification regulation heading; and (iii) devices that are described as "OTC" or "over the counter" devices in the FDA's product code name, the FDA's device classification name, or the "classification name" field in the FDA's device registration and listing database. The safe harbor also includes devices that qualify as DMEPOS (as described in Subpart C of 42 CFR part 414 (Parenteral and Enteral Nutrition) and Subpart D of 42 CFR part 414 (Durable Medical Equipment and Prosthetic and Orthotic Devices)) for which payment is available on a purchase basis under Medicare Part B payment rules (in accordance with the fee schedule published by Centers for Medicare and Medicaid Services (CMS)), and are (i) "prosthetic and orthotic devices," as defined in 42 CFR 414.202, that do not require implantation or insertion by a medical professional; (ii) "parenteral and enteral nutrients, equipment, and supplies" as defined in 42 CFR 411.351 and described in 42 CFR 414.102(b); (iii) "customized items" as described in 42 CFR 414.224; (iv) "therapeutic shoes," as described in 42 CFR 414.228(c); or (v) supplies necessary for the effective use of DME, as described in section 110.3 of chapter 15 of the Medicare Benefit Policy Manual (Centers for Medicare and Medicaid Studies Publication 100-02).

ANALYSIS

The determination of whether the medical device is a device of a type generally purchased by the general public at retail for individual use must be made on a facts and circumstances basis because it does not fall within a retail exemption safe harbor set forth in section 48.4191-2(b)(2)(iii).

Regularly Available for Purchase and Use by Individual Consumers

The medical device is regularly available for purchase and use by individual consumers who are not medical professionals under the relevant factors of section 48.4191-2(b)(2)(i). The fact that a doctor must prescribe the medical device for a patient is not a

factor in the determination that the device falls under the retail exemption. See Treas. Reg. § 48.4191-2(b)(2).

Consumers who are not medical professionals cannot purchase the medical device in person, over the telephone, or over the Internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell devices. See Treas. Reg. §48.4191-2(b)(2)(i)(A). Instead, a doctor must develop a treatment plan for a patient and then initiate purchase of the medical device from Medical Device Company, .

Consumers can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional. See Treas. Reg. § 48.4191-2(b)(2)(i)(B). Even though the medical device is prescribed by and ordered by a doctor, it is

.

The medical device is not classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medicine Devices). See Treas. Reg. § 48.4191-2(b)(2)(i)(C).

Primarily for Use in a Medical Institution or Office or by a Medical Professional

The design of the medical device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional under the relevant factors of section 48.4191-2(b)(2)(ii).

The medical device is

. Therefore, the medical device does not need to be implanted, inserted, operated, or otherwise administered by a medical professional. See Treas. Reg. § 48.4191-2(b)(2)(ii)(A).

The cost to acquire, maintain, and use the medical device does not require a large initial investment or ongoing expenditure that is not affordable for the average individual consumer. See Treas. Reg. § 48.4191-2(b)(2)(ii)(B); cf. Treas. Reg. § 48.4191-2(b)(2)(iv), Exs. 5, 9, 13, 14, and 15. The medical device is not a Class III device under the FDA system of classification. See Treas. Reg. § 48.4191-2(b)(2)(ii)(C). Furthermore, the medical device is not classified by the FDA under a category described in section 48.4191-2(b)(2)(ii)(D) of the regulations, nor is it a device described in section 48.4191-2(b)(2)(ii)(E) of the regulations.

The medical device has one factor under section 48.4191-2(b)(2)(i) that tends to show it is not regularly available for purchase and use by individual consumers, and none of the factors under section 48.4191-2(b)(2)(ii) of this section tend to show that the medical device is designed primarily for use in a medical institution or office or by medical

professionals. Therefore, based on the totality of the facts and circumstances, we conclude that the medical device falls within the retail exemption of section 4191(b)(2)(D).

This writing may contain privileged information. Any unauthorized disclosure of this writing may undermine our ability to protect the privileged information. If disclosure is determined to be necessary, please contact this office for our views.

If you have any questions concerning this memorandum, please contact Amanda F. Dunlap at (202) 317-6855.