



The Medical Device Tax & Dental Laboratory made Devices

The vast majority devices made by domestic dental laboratories do not meet the IRS's proposed definition of a "Taxable Medical Device" as proposed in § 48.4191-2.

Background

Dental Laboratories make crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers and sleep apnea devices and snore guards. The materials and components used to make these items (such as alloys, ceramic, resins, abutments, individual denture teeth, etc.) are listed with the FDA using FDA product codes.

With the exception of sleep apnea devices and snore guards, the devices that are domestically made by dental laboratories from the FDA listed and FDA product coded components are not required to be listed with the FDA and do not have any FDA product code. For example there is not a code for a porcelain-fused-to-metal crown or for a finished set of dentures or a completed dental implant.

While the FDA requires all establishments that manufacture medical devices to register with the FDA and requires these establishments to list the devices that they manufacture with the FDA pursuant to 21 CFR 807, dental laboratories are specifically exempted.

§ 807.65(i) exempts domestic dental laboratories from the FDA's device listing requirements. However, if a dental laboratory undertakes certain activities, such as importing devices or manufacturing sleep apnea devices or snore guards, the dental laboratory will be required to register with the FDA and list those devices with the FDA using the applicable FDA product code(s). Imported crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers are required to be listed with the FDA and do have an applicable FDA product code.

It is important to note that the IRS definition of importer that applies to excise taxes is different from the FDA's importer definition. Under the IRS definition of "importer" the person who brings an article into the United States is only a nominal importer if they are not also the beneficial owner of the article. For example, if you engage a customs broker they are a nominal importer and the IRS deems the beneficial owner to be the importer for excise tax purposes. See **26 CFR 48.0-2(a)(4)** for the IRS definition of "importer."

Taxable Medical Device – IRS Guidance to date

§ 48.4191–2 Taxable medical device. (as currently proposed by the IRS)

(a) *Taxable medical device*—(1) *In general*. A taxable medical device is any device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for humans. For purposes of this section, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act that is intended for humans means a device that is listed as a device with the Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, pursuant to FDA requirements. (emphasis added)

As stated in the IRS’s commentary that was published in the preamble of proposed rule:

“Therefore, all devices that are listed under a single product code listing in conjunction with the FDA’s device listing requirement are “taxable medical devices” unless they fall within an exemption under section 4191(b)(2).” *77 Fed. Reg. 25 (7 February 2012) p. 6029*

The IRS clearly states that any device listed under a single FDA product code is a “taxable medical device”. The IRS does not anywhere in the proposed rules or in the accompanying commentary or elsewhere indicate that anything other than a device that is required to be listed is a “taxable medical device”.

FDA Dental Device Product Codes

In 21 CFR 872 the FDA has promulgated the 132 generic classifications of the dental devices intended for human use that are in commercial distribution. Each one of these generic classifications has one or more associated three-letter FDA product codes. There are 297 three letter FDA product codes that apply to dental devices.

21 CFR 872 - Dental device classifications:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=872>

FDA Dental Device Product Codes:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&Submission_Type_ID=&DeviceName=&ProductCode=&DeviceClass=&ThirdParty=&Panel=DE&RegulationNumber=&PAGENUM=500&SortColumn=DeviceName

Dental device establishments that are required to register use these 297 FDA product codes in order to list with the FDA the devices they manufacture. There are no applicable FDA product codes for domestically made crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers.

Conclusion

Domestically made crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers are generally not required to be listed with the Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, pursuant to FDA requirements. Therefore, domestically made crowns, bridges, dentures, dental implants, mouth guards and orthodontic devices such as retainers are not “taxable medical devices” for the purposes of the Medical Device Tax.

PLEASE SHARE THIS ANALYSIS WITH YOUR OR LEGAL OR TAX ACCOUNTING PROFESSIONAL TO DETERMINE ITS APPLICABILITY TO YOU INDIVIDUAL BUSINESS ACTIVITIES.

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