

Internal Revenue Service

Number: **201601008**

Release Date: 12/31/2015

Index Number: 4191.00-00, 4221.01-00

Department of the Treasury

Washington, DC 20224

Third Party Communication: None

Date of Communication: Not Applicable

Person To Contact:

, ID No.

Telephone Number:

Refer Reply To:

CC:PSI:B7

PLR-115614-14

Date:

August 18, 2015

In Re:

LEGEND

X =

A =

System =

Software =

Dear :

This is in response to your authorized representative's request for a private letter ruling regarding the applicability of the medical device excise tax to certain transactions.

According to the facts submitted, X sells System and X develops Software for use with System.

A is in the business of marketing, distributing, and selling healthcare-related products.

A sells and sets up System pursuant to a reseller agreement (Agreement) with X.

Under the terms of Agreement, X grants A a license to install and use Software to set up System.

A does not list System or Software as a device with the FDA.

RULING REQUESTED

A's set up of System, pursuant to the terms of Agreement, does not constitute further manufacture within the meaning of § 4221.

LAW

Section 4191(a) imposes a tax on the sale of any taxable medical device by the manufacturer, producer, or importer of 2.3 percent of the price for which the device was sold.

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

Section 4221(a)(1) provides that no tax shall be imposed under chapter 32 on the sale by the manufacturer of an article for use by the purchaser for further manufacture, or for resale by the purchaser to a second purchaser for use by such second purchaser in further manufacture.

Section 4221(d)(6)(A) provides that an article shall be treated as sold for use in further manufacture if such article is sold for use by the purchaser as material in the manufacture or production of, or as a component part of, another article taxable under chapter 32 to be manufactured or produced by him.

Under § 48.4191-2(a) of the Regulations, a device defined in § 201(h) of the FFDCA that is intended for humans is a device that is listed as a device with the FDA under § 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements.

Under § 48.4221-2(b), an article shall be treated as sold for use in further manufacture if the article is sold for use by the buyer as material in the manufacture or production of, or as a component part of, another article taxable under chapter 32 of the Code. An article is used as material in the manufacture or production of, or as a component of, another article if it is incorporated in, or is a part or accessory of, the other article when the other article is sold by the manufacturer.

ANALYSIS AND CONCLUSION

Section 4221(d)(6)(A) provides, in part, that an article is treated as sold for use in further manufacture if the article is sold for use by the purchaser as material in the manufacture or production of, or as a component part of, another article taxable under chapter 32. In this case, A does not produce another article that is taxable under chapter 32 because A does not list System as a device with the FDA. Therefore, we conclude that A's set

up of System pursuant to Agreement does not constitute further manufacture within the meaning of § 4221.

This ruling is directed only to the taxpayer requesting it. Section 6110(k)(3) provides that it may not be used or cited as precedent.

Except as expressly ruled herein, no opinion is expressed or implied concerning the tax consequences of any aspect of any transaction or article discussed or referenced in this letter. Specifically, we express no opinion on whether a person that installs Software on one or more computers to create a System is a manufacturer. Further, we express no opinion regarding the § 4191 tax liability of anyone other than A with respect to System and Software.

In accordance with the Power of Attorney on file with this office, a copy of this letter is being sent to your authorized representative.

This private letter ruling is based upon information and representations submitted by Taxpayer and accompanied by a penalty of perjury statement executed by an appropriate party. While this office has not verified any of the material submitted in support of the request for a ruling, the supporting material is subject to verification or examination.

Sincerely,

Stephanie Bland
Branch Chief, Branch 7
Office of Associate Chief Counsel
(Passthroughs & Special Industries)