PRIVATE TAXPAYER RULING LR13-010

July 16, 2013

This private taxpayer ruling is in response to your letter dated May 11, 2012, as supplemented by your letter dated June 8, 2012, in which you requested a private taxpayer ruling on behalf of . . . (the "Company"). Specifically, you requested a determination of the applicability of Arizona's transaction privilege and use taxes to sales of Company's product . . . ("Product X") to hospitals and orthopedic surgery centers located in Arizona. Pursuant to Arizona Revised Statutes ("A.R.S.") § 42-2101, the Department may issue private taxpayer rulings to taxpayers and potential taxpayers on request.

Issue

Whether the sale of Product X to hospitals and surgery centers located in the state of Arizona is subject to transaction privilege tax or use tax?

Ruling

The Department concludes that Product X meets the definition of a prosthetic appliance for purposes of the exemptions provided under A.R.S. § 42-5061(A)(9) and A.R.S. § 42-5159(A)(17) and therefore, sales to hospitals and surgery centers located in the state of Arizona are exempt from tax.

This private taxpayer ruling does not extend beyond the facts presented in your letters dated May 11, 2012 and June 8, 2012.

Statement of Facts

The following is excerpted from your May 11, 2012 letter:

> Company is a biotechnology company specializing in the development and commercialization of innovative drug-device combination products to promote the healing of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury applications.
>
> Product X has been approved by the FDA as a Class II device.
>
> Product X is a sterile, synthetic, non-pyrogenic material intended for use in combination with autologous bone marrow for bone void filling and fracture repair of the pelvis and extremities.

> The product material is a composition of carbonated apatite and bovine type I collagen. Carbonated apatite is a form of calcium phosphate that closely resembles the mineral phase of natural human bone. The granules are interspersed within the collagen, providing an enhanced osteoconductive scaffold to support bone remodeling. The scaffold is highly porous with ample surface area for absorption of bone marrow aspirate ("BMA") and stem cell attachment.
>
> The Product X family is available in a variety of configurations, including: pads, strips, blocks, plugs and paste.
>
> Upon saturation with BMA, Product X may be manipulated as desired. This flexible structure allows the grafts to be shaped based on patient anatomy and surgical environment. Pads, strips, blocks and plugs may be compressed, folded, trimmed or layered. Hydrated paste may be molded.
>
> Company will sell Product X to hospitals and orthopedic surgery centers in the state for use in surgery. Product X is not sold or dispensed directly to the patient.

The following is excerpted from your June 8, 2012 letter:

> Product X is intended for orthopedic applications as filler for gaps and voids and fracture repair of the pelvis and the extremities. The FDA approved Product X for prescription use only.

Discussion & Legal Analysis

A.R.S. § 42-5061 imposes the transaction privilege tax under the retail classification. The retail classification is comprised of the business of selling tangible personal property at retail. A.R.S. § 42-5155 levies an excise tax on the storage, use or consumption in this state of tangible personal property purchased from a retailer or utility business, as a percentage of the sales price.

A.R.S. § 42-5061(A)(9) exempts from the retail classification "[p]rosthetic appliances as defined in § 23-501 prescribed or recommended by a health professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17 or 29." These chapters refer to podiatrists, doctors of chiropractic, dentists, physicians and surgeons, naturopathic physicians, nurses, osteopathic physicians and surgeons, and homeopathic physicians. Similarly, A.R.S. § 42-5159(A)(17) exempts from Arizona's use tax "[p]rosthetic appliances, as defined in A.R.S. § 23-501, prescribed or recommended by a person who is licensed, registered or otherwise professionally credentialed as a physician, dentist, podiatrist, chiropractor, naturopath, homeopath, nurse or optometrist." A.R.S. § 23-501(7), in turn, defines a "prosthetic appliance" as "an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ." Arizona Administrative Code (A.A.C.) R15-5-156(A)(12) further defines a "prosthetic appliance" as "an artificial device that fully or

partially replaces a part or function of the human body or increases the acuity of a sense organ."

Product X is a synthetic bone graft. More specifically, Product X is a sterile, synthetic, non-pyrogenic material intended for use in combination with autologous bone marrow for bone void filling of the pelvis and extremities. The 510(k) Summary "Description of the Device," included with your request, states the following: "The composite material is a resorbable, porous, osteoconductive bone graft matrix. The product is supplied dry in granular (putty) or block/strip form that is hydrated with autogenous bone marrow at the point of use. The product is sterile, non-pyrogenic, and for single use only."[1] As native bone grows, the native bone replaces the graft and results in a fully integrated region of new bone. Therefore, it appears that Product X meets the definition of a prosthetic appliance for purposes of the exemptions provided under A.R.S. § 42-5061(A)(9) and A.R.S. § 42-5159(A)(17). Sales to hospitals and surgery centers located in the state of Arizona are exempt from tax.

This response is a private taxpayer ruling and the determinations herein are based solely on the facts provided in the Request. Therefore, the conclusions in this private taxpayer ruling do not extend beyond the facts presented in your correspondence dated May 11, 2012 and June 8, 2012. The determinations are subject to change should the facts prove to be different on audit. If it is determined that undisclosed facts were substantial or material to the department's making of an accurate determination, this private taxpayer ruling shall be null and void. Further, the determination is subject to future change depending on changes in statutes, administrative rules, case law or notification of a different department position.

The determinations in this private taxpayer ruling are only applicable to the taxpayer requesting the ruling and may not be relied upon, cited nor introduced into evidence in any proceeding by a taxpayer other than the taxpayer who has received the private taxpayer ruling. In addition, this private taxpayer ruling only applies to transactions that occur or tax liabilities that accrue from and after the date the taxpayer receives the ruling.

[1] Each person who desires to market in the U.S. a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to the FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters. Before marketing a device, each submitter must receive an order, in the form of a letter, from the FDA which finds the device to be substantially equivalent and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.