

**TENNESSEE DEPARTMENT OF REVENUE
LETTER RULING # 12-28**

Letter rulings are binding on the Department only with respect to the individual taxpayer being addressed in the ruling. This ruling is based on the particular facts and circumstances presented, and is an interpretation of the law at a specific point in time. The law may have changed since this ruling was issued, possibly rendering it obsolete. The presentation of this ruling in a redacted form is provided solely for informational purposes, and is not intended as a statement of Departmental policy. Taxpayers should consult with a tax practitioner before relying on any aspect of this ruling.

SUBJECT

The application of the Tennessee sales and use tax exemption under TENN. CODE ANN. § 67-6-314(1) (2011) for prosthetic devices.

SCOPE

This letter ruling is an interpretation and application of the tax law as it relates to a specific set of existing facts furnished to the Department by the taxpayer. The rulings herein are binding upon the Department, and are applicable only to the individual taxpayer being addressed.

This letter ruling may be revoked or modified by the Commissioner at any time. Such revocation or modification shall be effective retroactively unless the following conditions are met, in which case the revocation shall be prospective only:

- (A) The taxpayer must not have misstated or omitted material facts involved in the transaction;
- (B) Facts that develop later must not be materially different from the facts upon which the ruling was based;
- (C) The applicable law must not have been changed or amended;
- (D) The ruling must have been issued originally with respect to a prospective or proposed transaction; and
- (E) The taxpayer directly involved must have acted in good faith in relying upon the ruling; and a retroactive revocation of the ruling must inure to the taxpayer's detriment.

FACTS

[TAXPAYER] (the "Taxpayer") is a biotechnology company specializing in [DESCRIPTION OF PRODUCTS].

[PRODUCT #1]

The Taxpayer sells [PRODUCT #1] which is a combination product [REDACTED]. The Taxpayer will sell [PRODUCT #1] to hospitals and surgery clinics in Tennessee for use in [REDACTED] surgeries.

[PRODUCT #1] is placed on defects, such as gaps between bones where a surgeon is trying to achieve fusion. It provides a scaffold for natural occurring tissue (bone) regeneration and is gradually resorbed by the body and turned into bone. [PRODUCT #1] was developed as a fully synthetic replacement to autograft in [REDACTED] surgery. [PRODUCT #1] consists of [NUMBER OF] components: [REDACTED]. It is supplied as a kit for a single use only.

At the point of use, [NUMBER OF] components are combined in entirety, mixed and subsequently applied to the surgical site. The [REDACTED] component of [PRODUCT #1] is a highly porous, reabsorbable and osteoconductive scaffold which provides a framework for bone regeneration, aids in preventing soft tissue infiltration and promotes stabilization of blood clots. The [COMPONENT] acts by stimulating the recruitment and proliferation of a variety of cell types.

[PRODUCT #2]

The Taxpayer also sells [PRODUCT #2], which 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 [PARTS OF THE BODY]. [REDACTED]. The Taxpayer will sell [PRODUCT #2] to hospitals and [REDACTED] surgery centers in Tennessee for use in surgery.

The product material is a composition of [COMPONENTS]. [COMPONENT] is [REDACTED], providing an enhanced osteoconductive scaffold to support bone remodeling. The [PRODUCT #2] product family is available in a variety of configurations: pads, strips, blocks, plugs, and paste.

Upon saturation with bone marrow aspirate, [PRODUCT #2] may be manipulated as desired. The 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.

RULINGS

1. Are sales of [PRODUCT #1] to hospitals and surgery centers exempt for purposes of the Tennessee sales and use tax?

Ruling: Yes. [PRODUCT #1] is exempt from the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-314(1) (2011) as a prosthetic device.

2. Are sales of [PRODUCT #2] to hospitals and surgery centers exempt for purposes of the Tennessee sales and use tax?

Ruling: Yes. [PRODUCT #2] is exempt from the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-314(1) (2011) as a prosthetic device.

ANALYSIS

Under the Retailers' Sales Tax Act, TENN. CODE ANN. §§ 67-6-101 to -907 (2011 & Supp. 2012), the retail sale in Tennessee of tangible personal property, including medical devices and supplies, is subject to sales and use tax unless an exemption from taxation applies.

TENN. CODE ANN. § 67-6-314(1) (2011) exempts from the Tennessee sales and use tax “prosthetic devices for human use and repair services for the repair and maintenance of those prosthetic devices.” The term “prosthetic device” is defined as “a replacement, corrective, or supportive device . . . worn in or on the body to: (i) [a]rtificially replace a missing portion of the body; (ii) [p]revent or correct physical deformity or malfunction; or (iii) [s]upport a weak or deformed portion of the body.” TENN. CODE ANN. § 67-6-102(70)(A) (Supp. 2012).

For the reasons discussed below, [PRODUCT #1] and [PRODUCT #2] are each exempt from the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-314(1) as a prosthetic device.

1. [PRODUCT #1]

[PRODUCT #1] is exempt from the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-314(1) as a prosthetic device.

For [PRODUCT #1] to be exempt from the sales and use tax under TENN. CODE ANN. § 67-6-314(1), the product must: (1) be for human use; (2) constitute a replacement, corrective, or supportive device; (3) be worn in or on the body; and (4) be used to artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.

The first requirement is satisfied because [PRODUCT #1] is for human use. The facts indicate that the product is used as a replacement to autograft in [REDACTED] surgery.

The second requirement is satisfied because [PRODUCT #1] constitutes a replacement, corrective, or supportive device. The facts indicate that [PRODUCT #1] provides a scaffold for bone tissue regeneration. The product therefore acts as a supportive device.

The third requirement is satisfied because [PRODUCT #1] is worn in or on the body. The product is applied to the surgical site inside or on the patient's body.

The fourth requirement is satisfied because [PRODUCT #1] is used to artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body. The facts indicate that [PRODUCT #1] is placed on defects, such as gaps between bones where a surgeon is trying to achieve fusion. The product therefore artificially replaces a missing portion of the bone inside the body. The product also prevents physical deformity or malfunction by aiding in the prevention of soft tissue infiltration. Additionally, the facts indicate that [PRODUCT #1] provides a scaffold for bone tissue

regeneration. The product therefore supports a weak or deformed portion of the body, *i.e.*, the [PART OF THE BODY] being repaired in surgery.

Accordingly, the sale of [PRODUCT #1] to hospitals and surgery centers is exempt for purposes of the Tennessee sales and use tax.

2. [PRODUCT #2]

[PRODUCT #2] is exempt from the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-314(1) as a prosthetic device.

For [PRODUCT #2] to be exempt from the sales and use tax under TENN. CODE ANN. § 67-6-314(1), the product must: (1) be for human use; (2) constitute a replacement, corrective, or supportive device; (3) be worn in or on the body; and (4) be used to artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.

The first requirement is satisfied because [PRODUCT #2] is for human use. The facts indicate that the product is used in surgery for bone void filling and fracture repair of the [PARTS OF THE BODY].

The second requirement is satisfied because [PRODUCT #2] constitutes a replacement, corrective or supportive device. The facts indicate that [PRODUCT #2] is used to provide an enhanced osteoconductive scaffold to support bone remodeling. The product therefore acts as a supportive device.

The third requirement is satisfied because [PRODUCT #2] is worn in or on the body. The product is available as pads, strips, blocks, plugs, and paste, and may be compressed, folded, trimmed, layered, or molded, as necessary, to conform to the patient's anatomy, which indicates it is worn either in or on the body.

The fourth requirement is satisfied because [PRODUCT #2] is used to artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body. The facts indicate that the product is used for bone void filling, and provides an enhanced osteoconductive scaffold to support bone remodeling. As a bone void filler, the product artificially replaces a missing portion of the body. Additionally, the product prevents physical deformity or malfunction by supporting bone remodeling. The product also supports a weak or deformed portion of the body, *i.e.*, the [PART OF THE BODY] being repaired in the surgery.

Accordingly, the sale of [PRODUCT #2] to hospitals and surgery centers is exempt for purposes of to the Tennessee sales and use tax.

Kristin Husat
General Counsel

APPROVED: Richard H. Roberts
Commissioner of Revenue

DATE: November 19, 2012