TENNESSEE DEPARTMENT OF REVENUE
LETTER RULING # 11-47

WARNING

Letter rulings are binding on the Department only with respect to the individual taxpayer being addressed in the ruling. This presentation of the ruling in a redacted form is informational only. Rulings are made in response to particular facts presented and are not intended necessarily as statements of Department policy.

SUBJECT

The application of the Tennessee sales and use tax to a device used in the repair of the mitral valve.

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

[PARENT COMPANY] and its wholly owned subsidiaries are engaged in the manufacture and sale of medical devices, including the design, development, and manufacture of a device known as [DEVICE]. [TAXPAYER] makes sales of the [DEVICE] to third party customers.

The [DEVICE] is a percutaneous device designed to perform an edge-to-edge reconstruction of the insufficient mitral valve while the heart is beating, as an alternative to the conventional surgical approach. The [DEVICE] enables the repair of the mitral valve in the treatment of

patients suffering from the effects of functional and degenerative mitral regurgitation, which is the most common type of heart valve disease in the United States. Many high risk surgical patients and non-surgical patients continue to be affected by the chronic volume overload caused by mitral regurgitation. The condition requires the heart to work harder and may ultimately lead to heart failure. Using the [DEVICE], the health care professional repairs the mitral valve without resorting to open heart surgery. Because the less invasive [DEVICE] procedure does not require an open chest incision or the use of a heart-lung machine, patients may avoid complications associated with surgery.

The [DEVICE] consists of two major components: 1) a steerable guide catheter; and 2) a clip delivery system, which includes the [DEVICE] (multiple [DEVICES] may be used in a single procedure where warranted). The [DEVICE] is sold by prescription only, on a "price per procedure" basis for a single charge. The steerable guide catheter and the clip delivery system are essential to implanting the [DEVICE] and have no independent use; as such, neither item is available independently in the marketplace.

The [DEVICE] is placed on the mitral valve leaflets, resulting in permanent leaflet approximations and a double mitral valve orifice. The [DEVICE] remains in the body permanently. The [DEVICE] is made of [MATERIALS]. The device is preassembled to the tip of the clip delivery system via a gripper line, lock line, and actuator connection to a threaded stud. The procedure is performed with echocardiographic and fluoroscopic guidance while the patient is under general anesthesia.

To access the left atrium of the heart, a standard transseptal crossing technique is performed by the implanting physician. The steerable guide catheter is inserted into the femoral vein and delivered to the left atrium via a guidewire. The clip delivery system is then inserted into the steerable guide catheter and the [DEVICE] is properly positioned over the mitral valve. Manipulation of the steering mechanism on the handles of the catheter and the clip delivery system positions the [DEVICE] down to the mitral valve. The [DEVICE] is actuated through manipulation of levers on the handle of the clip delivery system. When placement is successful, the [DEVICE] is closed and deployed from the clip delivery system. If placement of one device is insufficient, a second device may be put in place.

QUESTION

For purposes of the Tennessee sales and use tax, is the [DEVICE] exempt as a prosthetic device under TENN. CODE ANN. § 67-6-314(1) (Supp. 2010)?

RULING

Yes. The [DEVICE] is exempt for purposes of the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-314(1) (Supp. 2010) as a prosthetic device.

ANALYSIS

Under the Retailers' Sales Tax Act, TENN. CODE ANN. § 67-6-101 *et seq.*, the retail sale in Tennessee of tangible personal property, such as the MitraClip® System, is subject to sales and use tax, unless an exemption from taxation applies.

TENN. CODE ANN. § 67-6-314(1) (Supp. 2010) provides an exemption from the sales and use tax for "[p]rosthetic devices for human use and repair services for the repair and maintenance of those prosthetic devices." TENN. CODE ANN. § 67-6-102(73)(A) (Supp. 2010) defines the term "prosthetic device" as "a replacement, corrective, or supportive device including repair and replacement parts for the replacement, corrective, or supportive device worn on or in the body," which is used for one of the following purposes: 1) to artificially replace a missing portion of the body; 2) prevent or correct physical deformity or malfunction; or 3) support a weak or deformed portion of the body.[1]

Thus, for the retail sale of the [DEVICE] to be exempt from the sales and use tax under TENN. CODE ANN. § 67-6-314(1), the [DEVICE] must: 1) be for human use; 2) constitute a replacement, corrective, or supportive device; 3) be worn on or in 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.

On an initial note, the Department has taken the position that a disposable wire or similar item that is attached to and delivers an exempt medical device is treated as a single item, along with the medical device, for purposes of the exemption under TENN. CODE ANN. § 67-6-314(1). The [DEVICE] consists of two major components: 1) a steerable guide catheter; and 2) a clip delivery system, which includes the [DEVICE]. The steerable guide catheter and the clip delivery system are essential to implanting the [DEVICE] and have no independent use; as such, neither item is available independently in the marketplace. Accordingly, the entire [DEVICE] is treated as a single item for purposes of the exemption.

The first requirement under TENN. CODE ANN. § 67-6-314(1) is met because the [DEVICE] is for human use.

The second requirement is met because the [DEVICE] is a corrective device. An insufficient mitral valve results in functional and degenerative mitral regurgitation, which is the most common type of heart valve disease in the United States. This condition requires the heart to work harder and may ultimately lead to heart failure. The [DEVICE] corrects this defect and enables the valve to function properly.

The third requirement is met because the [DEVICE] is worn in the body. The [DEVICE] is placed on the mitral valve leaflets, resulting in permanent leaflet approximations and a double mitral valve orifice. The [DEVICE] remains in the body permanently.[2]

The fourth requirement is met because the [DEVICE] corrects a physical deformity or malfunction and supports a weak or deformed portion of the body. As discussed above, the [DEVICE] corrects a defective mitral valve and enables the valve to function properly.

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[1] Although not relevant to this letter ruling, TENN. CODE ANN. § 67-6-102(73)(B) excludes corrective eyeglasses and corrective lenses from the definition of a "prosthetic device." Additional information about the application of the Tennessee sales and use tax to specific healthcare products can be found on the Department's website at http://state.tn.us/revenue/streamlined/healthcarelist0108.pdf.

[2] Devices implanted in the body are considered as being "worn" in the body. *See Cordis Corp. v. Taylor*, 762 S.W.2d 138, 139 (Tenn. 1988) (finding an implantable cardiac pacemaker to be a prosthetic under a prior version of the exemption).

Accordingly, the [DEVICE] is exempt for purposes of the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-314(1) as a prosthetic device.

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APPROVED: Richard H. Roberts
Commissioner of Revenue

DATE: 9-12-11