ST 11-0002-PLR 02/07/2011 MEDICAL APPLIANCES

A medical appliance is defined as an item which is intended by its manufacturer for use in directly substituting for a malfunctioning part of the body. (This is a PLR) See 86 Ill. Adm. Code 130.311.

February 7, 2011

Dear Xxxxx:

This letter is in response to your letter dated July 7, 2010, in which you requested a Private Letter Ruling. The Department issues two types of letter rulings. Private Letter Rulings ("PLRs") are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department's regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter ("GIL") is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at www.tax.illinois.gov to review regulations, letter rulings and other types of information relevant to your inquiry.

Review of your request disclosed that all the information described in paragraphs 1 through 8 of Section 1200.110 appears to be contained in your request. This Private Letter Ruling will bind the Department only with respect to BUSINESS for the issue or issues presented in this ruling, and is subject to the provisions of subsection (e) of Section 1200.110 governing expiration of Private Letter Rulings. Issuance of this ruling is conditioned upon the understanding that neither BUSINESS nor a related taxpayer is currently under audit or involved in litigation concerning the issues that are the subject of this ruling request. In your letter you have stated and made inquiry as follows:

> We are writing to request a binding Private Letter Ruling (PLR) with respect [sic] the exemption from Retailers' Occupation Tax on the sale of a PRODUCT in the State of Illinois.
>
> Please be advised that the issues presented in this request are not involved in any audit, litigation, previous ruling request or other matter pending before the Illinois Department of Revenue. The tax period at issue is 2010 forward.
>
> To the best of taxpayer's knowledge, the Department has not previously ruled on this same or similar issue, and taxpayer has not previously submitted and withdrawn a ruling request on the same or similar issue.

Also please delete the following information from the PLR before publication dissemination: company name; address, headquarters and manufacturing locations; product names; contact names; phone numbers; and signature lines.

**Background:**

BUSINESS and its wholly owned subsidiaries are engaged in the manufacture and sale of medical devices, including the design, development, and manufacture of a medical device known as a PRODUCT. [ABC's sales company, BUSINESS, is requesting this opinion, as the entity that makes sales to third party customers.] The PRODUCT enables the repair of the mitral valve in the treatment of patients suffering from the effects of functional and degenerative Mitral Regurgitation (MR). MR is the most common type of heart valve disease in the U.S. and around the world, affecting millions of people. Many high risk surgical patients and non-surgical patients continue to be affected by the chronic volume overload caused by MR, which requires the heart to work harder, and may ultimately lead to heart failure.

Using the PRODUCT, the mitral valve is repaired without open heart surgery. Because the less invasive PRODUCT procedure does not require an open chest incision or the use of a heart- lung machine, patients may avoid the complications long associated with surgery.

**PRODUCT:**

The system consists of two major components:

- A steerable Guide Catheter, and
- A Clip Delivery System.

**Underlying Facts:**

The PRODUCT consists of a Steerable Guide Catheter, and a Clip Delivery System, which includes the PRODUCT device. The PRODUCT is sold by prescription only, on a price per procedure basis for a single charge. The procedure fee includes the PRODUCT, containing two interdependent components: the Steerable Guide Catheter and the Clip Delivery System, both of which are used for one procedure only (multiple PRODUCT devices may be utilized on a single procedure where warranted). The Clip Delivery System and Steerable Guide Catheter are a device set that are essential to implanting the PRODUCT device and have no independent use. As such, neither the Clip Delivery System nor the Steerable Guide Catheter exists in the marketplace.

**Procedure Description:**

The PRODUCT 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 PRODUCT includes a Steerable Guide Catheter and Clip Delivery System with a PRODUCT device that enables placement of the PRODUCT device on the mitral valve leaflets resulting in permanent (remains in the human body) leaflet approximation and a double mitral valve orifice. The PRODUCT device is made of PRODUCT and covered with a PRODUCT2 fabric to promote healing and is pre-assembled to the tip of the Clip Delivery System via the Gripper Line, Lock Line, and the Actuator connection to the 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 then inserted into the femoral vein and delivered into the left atrium via a guidewire. The Clip Delivery System is then inserted into the Steerable Guide Catheter and the PRODUCT device is properly positioned over the mitral valve. Manipulation of the steering mechanism on the handles of the Steerable Guide Catheter and the Clip Delivery System positions the PRODUCT device down to the mitral valve. The PRODUCT device is actuated (i.e., open and closed, locked, deployed) through manipulation of levers on the handle of the Clip Delivery System.

The following picture illustrates the PRODUCT:

[picture]

When placement is successful, the PRODUCT device is closed and deployed from the Clip Delivery System. If placement of one PRODUCT does not result in an acceptable reduction in MR, a second PRODUCT may be placed to further reduce MR. The physician will determine if there is adequate mitral valve orifice area to accommodate an additional PRODUCT without creating MV stenosis.

<u>Comparison of Steerable Guide Catheter to typical coronary guiding catheter:</u>
As the Steerable Guide Catheter has a very similar name to the commonly used coronary guiding catheter, a brief comparison of the two is provided:

The Steerable Guide Catheter for the PRODUCT procedure is designed to provide a pathway for the Clip Delivery System only.

- Its specific design is integral to the PRODUCT
- The Steerable Guide Catheter has an internal locking mechanism which allows the operator to maintain precise steering control over the Clip Delivery System while in the patient
- The Clip Delivery System cannot be used alone without the Steerable Guide Catheter
- The Clip Delivery System cannot be used in any other company's available guiding catheters
- The Steerable Guide Catheter is SIZE proximally and tapers down to SIZE at the distal end
- The construction allows for optimal support and consistent delivery of the Clip Delivery System
- COATING allows ease of introduction in the patient's leg and venous system.

Coronary guiding catheters are an extruded compound of plastic and nylon (nylon elastomeric jacket). The braiding (nylon), of a coronary catheter is meant to add some support to the catheter. These catheters tend to soften after a period of time in the body and may lose some of their supportive properties.

- Coronary guides typically are SIZE. That French size is consistent over the entire length of the catheter.
- Coronary guides have a soft atraumatic tip.

Coronary guiding catheters can be used to deliver:

1. balloon catheters
2. stents
3. drugs
4. ultrasound catheters
5. perfusion catheters
6. thrombus retrieving catheters
7. CTO wires
8. Radio Frequency wires and balloons

**Applicable rules:**

86 Ill. Adm. Code 130.310 (e)(2) defines a medical appliance as an item intended by its manufacturer for use directly in substituting for a malfunctioning part of the human body.

Under 35 ILCS 120/2-10, prescription medical appliances intended for human use are subject to the 1% reduced tax rate, plus local taxes.

**Issue Presented:**

Does the PRODUCT qualify as a corrective medical appliance, and thus subject to the reduced 1% State tax rate, under 86 Ill. Adm. Code 130.310 (e)(2), as the PRODUCT device is permanently implanted in the human body to correct a malfunctioning mitral valve, and the Steerable Guide Catheter and the Clip Delivery System are integral and necessary parts of the PRODUCT, which is only sold by prescription as a single item and cannot function except as a complete system.

**Conclusion:**

The PRODUCT qualifies as a corrective medical appliance subject to the reduced 1% State rate.

Taxpayer is not aware of any applicable contrary authorities.

If you have questions regarding this request, or anticipate issuing a ruling that tax would be due at the high rate, please contact me.

**DEPARTMENT'S RULING:**

Please see the Department's regulation at 86 Ill. Adm. Code Section 130.311, which are its regulations governing Drugs, Medicines, Medical Appliances and Grooming and Hygiene Products. Those products that qualify as drugs, medicines and medical appliances are taxed at a lower State rate of 1% plus any applicable local taxes. Those items that do not qualify for the low rate of tax are taxed at the general merchandise rate of 6.25% plus applicable local taxes.

A medicine or drug is any pill, powder, potion, salve, or other preparation for human use that purports on the label to have medicinal qualities. A written claim on the label that a product is intended to cure or treat disease, illness, injury or pain, or to mitigate the symptoms of such disease, illness, injury or pain constitutes a medicinal claim. See Section 130.311 for examples of medicinal claims. Beginning on September 1, 2009, the term "nonprescription medicines and drugs" does not include grooming and hygiene products. Grooming and hygiene products include, but are not limited

to, soaps and cleaning solutions, shampoo, toothpaste, mouthwash, antiperspirants, and sun tan lotions and screens, unless those products are available by prescription only. If an item is a nonprescription grooming and hygiene product, it will be taxed at the State 6.25% general merchandise rate regardless of any medicinal claims made on the product's label.

A medical appliance is an item that is intended by its manufacturer for use in directly substituting for a malfunctioning part of the human body. Included in the exemption as medical appliances are such items as artificial limbs, dental prostheses and orthodontic braces, crutches and orthopedic braces, wheelchairs, heart pacemakers, and dialysis machines (including the dialyzer). Corrective medical appliances such as hearing aids, eyeglasses and contact lenses qualify for exemption.

Based upon the representations made in your letter, we believe the PRODUCT, which is sold as an integral unit as described in your letter, qualifies as a medical appliance and is, therefore, subject to the 1% State rate of tax plus any applicable local taxes.

The factual representations upon which this ruling is based are subject to review by the Department during the course of any audit, investigation, or hearing and this ruling shall bind the Department only if the factual representations recited in this ruling are correct and complete. This Private Letter Ruling is revoked and will cease to bind the Department 10 years after the date of this letter under the provisions of 2 Ill. Adm. Code 1200.110(e) or earlier if there is a pertinent change in statutory law, case law, rules or in the factual representations recited in this ruling.

I hope this information is helpful. If you have further questions concerning this Private Letter ruling, you may contact me at 782-2844. If you have further questions related to the Illinois sales tax laws, please visit our website at www.tax.illinois.gov or contact the Department's Taxpayer Information Division at (217) 782-3336.

Very truly yours,

Terry D. Charlton
Chairman, Private Letter Ruling Committee

TDC:msk