

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 June 10, 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:

BUSINESS requests a Private letter Ruling for the period ending June 30, 2008 as to the treatment of certain of its products as described below under section Title 86, Part 130, Section 130.310 as medical appliances subject to the 1% sales tax rate.

BUSINESS does not have an audit or litigation pending with the Illinois Department of Revenue at this time.

To the best of our knowledge the department has not previously ruled on the same or a similar issue for BUSINESS or a predecessor. BUSINESS or any representatives have not previously submitted the same or a similar issue to the Department.

Facts

BUSINESS manufactures and sells Medical Devices including stent systems. Our stent systems consist of expandable metal or plastic tube often in the form of mesh pre-

mounted on a delivery system. The stent system is designed and intended to treat hardening of the arteries caused by formation of multiple plaques within the arterial wall restricting blood flow. The stent is inserted into the lumen of the anatomical vessel to keep a previously blocked passageway open. The stent is designed to hold plaque against the arterial wall, opening up the blood vessel, and prevent a stroke from occurring.

The procedure for placing the stent in the vessel consists of inserting a guidewire into the vessel threading the stent system over the guidewire, releasing the stent from the delivery system and withdrawing the delivery system then the guidewire.

Please see Exhibits 1 and 2 for detailed information related to our stent systems.

Discussion

Medical Appliances defined under Title 86, part 130, Section 130.310 (e)(2) is an item that is intended by its manufacturer for use in directly substituting for a malfunctioning part of the human body. The following paragraphs describe opposing interpretations of this section.

The stent system does not qualify as a medical appliance because it does not directly substitute for the artery even though it is permanently implanted in the body. It restores the function of the artery but does not replace it. The stent is also not a stand alone [sic] product. A delivery system is required to be used to insert the stent into the body and be released into the arterial wall. The delivery system is then discarded after use. Based on the current cost of the stent system it has been determined that the delivery system represents between 51% and 52% of the manufacturing cost for stent system device.

The alternative view is that the stent substitutes for the artery. Without the stent there would be no blood flow and the artery would not function. In addition the stent is permanently implanted into the body so that the artery functions normally for an extended period of time. Although the delivery system represents over 50% of the manufacturing cost of the stent system, the implantable stent is the value-added part of the system which the customer is paying for. Since the stent substitutes for the artery, it should be considered a medical appliance and subject to the reduced sales tax rate of 1%.

Conclusion

The taxpayer requests a Private Letter Ruling determining if our stent system qualifies as a medical application by definition and should be charged at the lower rate of 1%.

Declaration- I declare, under the penalties set forth that this letter has been examined by me and, to the best of my knowledge and belief, is a true, correct, and complete statement, made in good faith, and pursuant to the laws, and rules issued.

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 two particular stent systems referred to in your Exhibits 1 and 2 attached to your letter, which are sold as an integral unit as described in your letter, qualify as medical appliances and are, 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/DB:msk