

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. See 86 Ill. Adm. Code 130.311(d). (This is a GIL.)

October 7, 2010

Dear Xxxxx:

This letter is in response to your letter dated March 31, 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.

The nature of your inquiry and the information you have provided require that we respond with a GIL. In your letter you have stated and made inquiry as follows:

On behalf of our client, (hereinafter referred to as 'Company' or 'the Company'), FIRM respectfully requests a Private Letter Ruling from the Illinois Department of Revenue (hereinafter referred to as 'Department' or 'the Department') as to the proper application of Illinois Retailers' Occupation Tax ('ROT') and Use Tax ('UT') to the transaction described below. An executed Power of Attorney form authorizing FIRM to represent the Company in this matter is enclosed. To the best of the knowledge of the Company and FIRM: (1) the Illinois Department of Revenue has not previously ruled on the same or similar issue for the Company or a predecessor; (2) the same or similar issue was not previously submitted and withdrawn by the Company or FIRM prior to the Department's issuance of a PLR; and (3) the Company is not under audit by or involved in litigation with the Department.

STATEMENT OF FACTS

The Company, incorporated in STATE, markets and distributes tangible personal property in Illinois. The Company has resident salespersons in the state that carry minimal amounts of 'trunk stock' inventory.

The Company is currently registered in Illinois for corporate income/franchise tax and withholding taxes. The Company is filing corporate income/franchise tax returns. The

Company is withholding on resident employees and is in compliance with the rules surrounding non-resident employees entering the state.

The Company has registered with the Department for sales/use tax purposes, files sales/use tax returns (historically and currently), and remits sales tax to the state. The Company was recently audited by the state on its sales and use tax filings.

Bone Growth Stimulation:

Human bone is a living tissue which has the inherent ability to heal itself when broken or injured, similar to skin. When a bone is broken, the broken bone helps promote the body's bone healing process by creating its own electrical field. This low level electrical field activates the body's own repair mechanism, which in turn stimulates bone healing. When the body's natural electrical field malfunctions during the bone healing process, application of an electrical stimulator can replace the body's natural bone healing process.

Bone growth stimulation is the technique of promoting bone growth in difficult to heal fractures, non-fusions and adjunct applications for high risk patients by applying a low electrical current to the fracture/fusion site. Some patients are at greater risk of not generating new bone around the damaged site because of failure of the biologic processes necessary for bone growth. Failures can occur for a variety of reasons, including local factors such as high-energy trauma, higher grade and open fractures, comminution of the fracture, vertical or oblique fracture pattern, and fracture displacement, and systemic factors, such as diabetes, heavy smoking, and vascular disease. For fusion patients, post-surgical application of bone growth stimulation has been shown to increase the probability of fusion, without the need for additional surgery, when the body is unable to heal the bone without outside intervention.

The Company's patented bone growth stimulators are portable, non-invasive, devices which use a low level of PEMF signals to activate the body's natural healing process and to stimulate bone growth in correcting fracture non-unions and to stimulate bone fusions when the body is unable to do so on its own. PEMF stands for Pulsed ElectroMagnetic Field and is a low-energy, time-varying magnetic field that has been proven effective in promoting bony arthrodeses in fracture non-unions and as an adjunct to surgical fusion for patients at high risk for non-fusion. In certain situations, fractures do not heal or heal slowly, resulting in 'non-unions.' In the case of a non-union fracture, the bone cells at the fracture site are malfunctioning and have slowed or ceased to produce bone. Orthopedists generally agree that in a non-union fracture, all healing processes have stopped, and healing can only be initiated by another procedure since no spontaneous healing will take place. Similarly, a patient at high risk for non-fusion may require a bone growth stimulator as an adjunct to fusion surgery to activate the body's natural bone healing and to increase the probability of fusion success, where a minimum of nine months has elapsed since the last surgery. Application of PEMF activates the body's natural repair mechanism when it is absent or not fully functional in certain patients, and enhances bone growth for successful outcomes. Clinical data shows that the Company's PEMF signal enhances the body's enzyme activities, induces mineralization, encourages new vascular penetration and results in a process that generates new bone growth and ultimately the healing of the non-union fracture/fusion.

The bone growth stimulator serves as a device that supports the healing of a movable part (as a joint or a fractured bone) by providing electrical stimulation to the broken bone. The external stimulation delivered by these apparatuses stimulates bone cells at the fracture/fusion site to produce insulin-like growth factors. These growth factors are small proteins which have the capability of directly stimulating bone cells to divide and produce collagen, which is the precursor to bone. These events stimulate the production of bone and ultimately the healing of the non-union fracture or fusion. In a normal healing situation, the body produces the growth factor without the need for external stimulation. This condition presents a serious health risk if the fracture is in a weight-bearing bone since failure to intervene and correct this situation often results in the amputation of a limb. Likewise if the fusion fails to heal the situation often results in decreased mobility and/or permanent disability

This ruling request respectfully requests the Department to make a written determination of whether the Company's product, as detailed below, qualifies for the reduced (low) sales/use tax rate for drugs and medical appliances as provided in Illinois sales tax laws.

RULING REQUESTED

Company's Illinois sales of bone growth stimulators at retail, as discussed below, qualify for the reduced (low) sales and use tax rate for drugs and medical appliances as provided in 35 ILCS §§ 120/2 and Ill. Admin. Code 130.310(e).

AUTHORITY AND ANALYSIS IN SUPPORT OF RULING REQUESTED

Illinois imposes the Retailer's [sic] Occupation Tax ('ROT') on persons, i.e., retailers, engaged in the selling of tangible personal property ('TPP') at retail in Illinois. 35 ILCS §§ 120/2. Illinois also imposes the Use Tax ('UT') on purchasers of TPP at retail for use in Illinois. 35 ILCS §§ 105/3. A seller that incurs ROT on a sale of TPP reimburses itself through the collection of the UT from the purchaser. 86 Ill. Admin. Code § 130.101(d). The ROT generally is imposed at a rate of 6.25% on sales of tangible personal property within the state.

However, the language in the relevant statute (35 ILCS § 120/2-10) provides for a reduced sales tax rate of 1% of the gross receipts from sales of 'prescription and nonprescription medicines, drugs, and medical appliances'. 86 Ill. Admin. Code § 130.310(e) defines 'medical appliance' for purposes of the reduced sales tax as:

[A]n 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 devices such as hearing aids, eyeglasses and contact lenses qualify for exemption.

In General Information Letter, ST-96-0518-GIL (Dec. 19, 1996) the Department determined that a bone growth stimulator was not a medical appliance, as a stimulator is used to enhance the healing of bone fractures and that they are not intended by their manufacturers to directly substitute for a malfunctioning part of the body. The

Department determined that they were used for treatment purposes and did not qualify for the low rate of tax as a medical appliance.

However, in General Information Letter, ST-98-0330-GIL (Oct. 26, 1998), the Department of Revenue provided an analysis in response to a request for a ruling that sales of bone growth stimulators were subject to a reduced sales tax rate under 35 ILCS § 120/2-10. As part of ST-98-0330-GIL, the Department stated:

In order to qualify as a medical appliance, the product must directly substitute for a malfunctioning part of the body. Some of the products specifically listed in the regulation as qualifying for the reduced rate are home glucose monitors, home blood glucose test strips and related supplies to treat human diabetes. Other products that directly substitute for a malfunctioning part of the body include urological catheters, leg bags, ostomy pouches and drain bags, and mastectomy prosthetic devices such as forms and bras.

Generally, tangible personal property, such as that described in your letter (i.e., bone growth stimulators), that allow the body to perform a function that it would normally perform but is currently not performing would qualify as medical appliances. Stated another way, as long as items are substituting for malfunctioning parts of the body, they qualify.

As discussed at length above, the bone growth stimulators substitute for the body's malfunctioning natural bone healing process. Therefore, under the Department's position outlined above, the stimulators should qualify as medical appliances for purposes of the reduced sales tax rate. The following are key facts relating to the noninvasive bone growth stimulation products:

- The Company's device can only be obtained by a patient with a written prescription from a licensed physician.
- The Company's bone growth stimulators correct the body's natural healing process and have proven successful in replacing the body's naturally occurring electrical currents to heal fracture non-unions and fusions. When the body's natural healing process is malfunctioning, the result can include fracture non-unions and failed fusions (i.e., bones that do not heal or heal improperly). The Company's bone growth stimulators correct the body's malfunctions by providing a substitute for the body's naturally occurring electrical field to properly heal bones. In these cases, the bone growth stimulator corrects the missing or reduced physical malfunction of healing within a broken bone. Application of PEMF activates the body's natural repair mechanism when it is absent or not fully functional in certain patients, and enhances bone growth for successful outcomes. The bone growth stimulators are items that are intended for use in directly substituting for the body's malfunctioning bone healing process, as required under 86 Ill. Admin. Code § 130.310(e).
- The bone stimulators sold by the Company are akin to pacemakers, which qualify as medical appliances for the reduced sales tax rate under 86 Ill. Admin. Code § 130.310(e). A pacemaker uses electrical impulses to regulate the beating of the heart when the heart is malfunctioning. The Company's bone stimulators provide

an artificial replacement for the natural electrical field normally created by a broken bone, when the natural electrical field is malfunctioning.

- The bone growth stimulator is classified as an FDA Class III device. An FDA Class III device is the most stringent regulatory category for devices. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Examples include:
 - o Replacement heart valves,
 - o Implanted cerebella stimulators,
 - o Implantable pacemaker pulse generators,
 - o Endosseous (intra-bone) implants
- The Company's bone growth stimulators must be used for at least three to nine months, depending on the application to be effective.

Because the bone growth stimulators replace the body's natural healing process when the process malfunctions, the Company's bone growth stimulator meets the requirements of the Illinois reduced sales tax rate provided in the statute and regulations.

CONCLUSION

Based upon the information provided above, we believe the Company's sales of bone growth stimulators in Illinois qualify as sales of medical appliances and therefore are subject to the reduced sales tax rate of 1% for medical appliances under 35 ILCS §§ 120/2 and Ill. Admin Code 130.310(e).

We respectfully request written confirmation, in the form of a Private Letter Ruling, that the above analysis and conclusion by the Company is consistent with the Department's analysis of the applicable Illinois law and regulations.

If you have any questions or require additional information from the Company in order to respond to this request, please do not hesitate to contact INDIVIDUAL. Thank you in advance for your attention to this matter.

DEPARTMENT'S RESPONSE:

The Department's regulation "Public Information, Rulemaking and Organization" provides that "[w]hether to issue a private letter ruling in response to a letter ruling request is within the discretion of the Department. The Department will respond to all requests for private letter rulings either by issuance of a ruling or by a letter explaining that the request for ruling will not be honored." 2 Ill. Adm. Code 1200.110(a)(4).

The Department has decided that it will not issue a Private Letter Ruling in regards to your request. The following general information should provide you with sufficient guidance regarding your request.

All gross receipts from sales of tangible personal property in Illinois are subject to Retailers' Occupation Tax unless an exemption is specifically provided. Medicines and medical appliances are

not taxed at the normal State rate of 6.25% plus applicable local taxes. These items are taxed at a reduced State rate of 1% plus applicable local taxes. See 86 Ill. Adm. Code 130.311. Items subject to this lower tax rate include prescription and nonprescription medicines, drugs, medical appliances, and insulin, urine testing materials, syringes, and needles used by diabetics, for human use.

The definition of a medical appliance is "an item which is intended by its manufacturer for use in directly substituting for a malfunctioning part of the body." "Medical appliances" may be prescribed by licensed health care professionals for use by a patient, purchased by health care professionals for the use of patients, or purchased directly by individuals. See 86 Ill. Adm. Code 130.311(d). Please note that not all items prescribed by or used by physicians or other licensed health care professionals qualify for the low rate.

Medical appliances that qualify for the reduced rate include such items as artificial limbs, dental prostheses and orthodontic braces, crutches and orthopedic braces, wheelchairs, heart pacemakers, and dialysis machines. Other examples of items that qualify for the reduced rate are corrective medical appliances such as hearing aids, eyeglasses and contact lenses. As a general proposition, diagnostic, treatment, and rehabilitative equipment items do not qualify for the reduced rate of tax as medical appliances because such items are not "used to directly substitute for a malfunctioning part of the human body", 86 Ill. Adm. Code 130.311(d).

As you can see, in order for a medical appliance to qualify for the reduced rate, the medical appliance itself must be used in a manner that directly substitutes for a malfunctioning part of the body. Based on the information you provided, it appears that your product would not qualify.

For your information, I would like to mention that the letters you reference in your letter, dated December 19, 1996 and October 26, 1998, are 12 to 15 years old, and are both General Information Letters which do not constitute statements of agency policy that apply, interpret or prescribe the tax laws administered by the Department. Moreover, General Information Letters are not binding on the Department, may not be relied upon by taxpayers in taking positions with reference to tax issues and create no rights for taxpayers under the Taxpayers' Bill of Rights Act. See 2 Ill. Adm. Code 1200.120 which can be found on the Department's website.

I hope this information is helpful. If you require additional information, please visit our website at www.tax.illinois.gov or contact the Department's Taxpayer Information Division at (217) 782-3336.

Very truly yours,

Debra M. Boggess
Associate Counsel

DMB:msk