

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. (This is a PLR.)

November 30, 2012

Dear:

This letter is in response to your letter dated June 21, 2012, in which you request 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 COMPANY, Inc. (FEIN X) 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 COMPANY, Inc. 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:

This is to request, on behalf of our client, COMPANY, Inc., an official letter ruling regarding the application of sales tax to the sale of its combination drug-device product, PRODUCT1 to hospitals and surgery centers in the state. A copy of our letter dated May 3, 2012 regarding one of the client's other products, PRODUCT2, is provided for your reference. It is acceptable to combine the two requests into one ruling as long as both products are separately analyzed and addressed. A copy of our power-of-attorney form is provided for your records.

Statement of Facts

- COMPANY is a biotechnology company specializing in the development and commercialization of innovative drug-device combination products to promote the healing of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury applications.
- The PRODUCT1 is a combination product pending marketing approval by the FDA as a Class 3 Medical Device.
- PRODUCT1 was developed as a fully synthetic replacement to autograft in hindfoot and ankle surgery.
- PRODUCT1 consists of two components: recombinant human platelet-derived growth factor (rhPDGF-BB) and beta-tricalcium phosphate (B-TCP). It is supplied as a kit for a

single use only. At the point of use, the two primary components are combined in entirety, mixed and subsequently applied to the surgical site.

- The B-TCP component of PRODUCT1 is highly porous, resorbable and osteoconductive scaffolded which provides a framework for bone regeneration, aids in preventing soft tissue infiltration and promotes stabilization of the blood clot.
- The recombinant human platelet-derived growth factor (rhPDGF-BB), also known as becaplermin, acts by stimulating the recruitment and proliferation of a variety of cell types.
- PRODUCT1 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. The presence of the protein stimulates this naturally occurring biological process.
- COMPANY will sell its product, PRODUCT1 to hospitals and surgery clinics in the state for use in hindfoot and ankle surgeries.

References

- Illinois Regulation 130.311(d)

Issue

- Based on the facts as presented, is the sale of PRODUCT1 to hospitals and surgery centers in the state subject to sales tax or use tax?

Disclaimers

- To our knowledge, COMPANY is not involved in an audit or litigation pending with the Department.
- To our knowledge, the Department has not previously ruled on the same or similar issue for COMPANY.
- To our knowledge, COMPANY has not previously requested a ruling on the same or similar issue but withdrew the request before the ruling was issued.

Your guidance and assistance in this tax matter will be greatly appreciated. If you have any questions and/or need additional information, please contact us directly at XX.

DEPARTMENT'S RULING:

Please see the Department's regulation at 86 Ill. Adm. Code Section 130.311, which is 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.

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." Please note that 86 Ill. Adm. Code 130.311(d)(7) provides that 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. Note, though, not all items prescribed by physicians or other licensed health care professionals qualify for the low rate. 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, even if prescribed by a licensed health care professional, because such items are not "for use in directly substituting for a malfunctioning part of the body," 86 Ill. Adm. Code 130.311(d).

Based upon the representations in your letter, we believe that PRODUCT1 qualifies for the lower State rate of 1% 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