

STATE OF COLORADO

DEPARTMENT OF REVENUE
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PLR-12-004

John W. Hickenlooper
Governor

August 21, 2012

Barbara J. Brohl
Executive Director

XXXXXXXXXXXXXXXXXX
ATTN: XXXXXXXXXX
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XXXXXXXXXXXXXXXXXX

Re: Private Letter Ruling

Dear XXXXXXXXX,

Your firm submitted on behalf of XXXXXXXXXXXXXXXXXXXXXXXX ("Company") a request for a private letter ruling to the Colorado Department of Revenue ("Department") pursuant to Regulation 24-35-103.5. This letter is the Department's private letter ruling.

Issues

Is Company's sale of Product to hospitals and surgery centers in Colorado subject to sales and use taxes?

Conclusion

Company's sale of Product to hospitals and surgery centers in Colorado is not subject to state sales and use taxes.

Background

Company is a biotechnology company specializing in the development and commercialization of drug-device products to promote healing of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury. XXXXXXXXXX ("Product") is a synthetic, non-progenic material used in combination with autologous bone marrow for bone void filling and fracture repair of the pelvis and extremities. Product is approved by the U.S. Food and Drug Administration as a Class II medical device and is available only by prescription. The two components used to create Product material closely resemble the mineral phase of natural human bone and provide an enhanced osteoconductive scaffold to support bone remodeling. The scaffold is highly porous with ample surface area for absorption of bone marrow aspirate ("BMA") and stem cell attachment.

Product is available in pads, strips, blocks, plugs and paste. Upon saturation of BMA, Product can be manipulated or molded as desired. The flexible structure of Product allows grafts to be shaped based on patient anatomy and surgical environment. Pads, strips, blocks and plugs can be compressed, folded, trimmed, or layered.

Discussion

Colorado levies sales and use tax on the sale or use of tangible personal property. §§39-26-104(1)(a) and 202, C.R.S. However, sales and use of certain medical products are exempt. There are at least three exemptions specifically related to the sale of medical equipment: (1) medical supplies furnished to a patient as part of a licensed provider's¹ professional services, (2) durable medical equipment, and (3) prosthetic devices. See generally, §39-26-717, C.R.S.

1. Materials Furnished as Part of a Licensed Provider's Professional Service

Sales of materials furnished by a licensed provider as part of his or her professional services to patients are exempt from sales and use tax. §39-26-717(1)(a), C.R.S. In order to qualify for this exemption, the material must leave the licensed provider's office with the patient.² For example, a catheter furnished by a doctor is exempt because it is furnished as part of the doctor's professional service to the patient and the catheter leaves the office with the patient.

Product is permanently absorbed by the bone tissue and, thus, leaves the doctor's office with the patient. In an analogous situation, we determined that casts and splints, which are used to heal broken bones, fall within this exemption when furnished to a patient by a physician as part of the physician's professional services and the items leave the physician's office with the patient. For these reasons, we find that Product is exempt as material furnished to a patient by a licensed provider as part of the provider's professional services to the patient.

Finally, you state that Product is sold to hospitals and surgery centers rather than to licensed providers. We believe it would be an unwarranted limitation of this exemption to limit its application only to those licensed providers who actually purchase the material. As a result, this exemption also applies to materials purchased by hospitals, medical clinics, or surgery centers, so long as the material is furnished by a licensed provider to a patient as part of the provider's professional service. Thus, we rule here that Company's sales of Product to hospitals and surgery centers under the circumstances described above are exempt.

2. Durable Medical Equipment

¹ "License provider" means any person authorized to prescribe drugs under the provisions of title 12, C.R.S., and includes, but is not limited to: physicians, dentists, podiatrists, advanced practical nurse, physician assistants, and veterinarians.

² See, FYI Sales 68 "Medical and Dental Supplies and Equipment," p. 3, "Licensed Providers." You can view this publication on the Department's web site at www.colorado.gov/revenue/tax > Tax Library > FYI Publications > Sales > Sales 68.

Colorado also exempts the sale of durable medical equipment. Durable medical equipment means equipment, including repair and replacement parts for such equipment, dispensed pursuant to a prescription by a licensed physician, physician's assistant, or advanced practice nurse with prescriptive authority, and that:

- a. can withstand repeated use;
- b. Is primarily and customarily used to serve a medical purpose;
- c. Is generally not useful to a person in the absence of illness or injury, and
- d. Is not worn in or on the body.

§ 39-26-717(2)(a), C.R.S. Product does not qualify for this exemption because it cannot withstand repeated use and it is worn in the body.

3. Prosthetic Device

It is not clear whether the sale of Product qualifies for the prosthetic device exemption. A prosthetic device is an artificial part which either aids or replaces a bodily function and is designed, manufactured, or adjusted to fit a particular individual.³ In some sense, Product replaces a body part by creating a framework over which bone grows to fill voids and repair fractured bones. This artificial framework remains after the bone has healed. However, this framework is largely superseded by the new bone growth and strikes us more as a means by which the body, itself, heals, much like a splint or bandage allows the body to heal itself, rather than providing a replacement for a body part.

Product can arguably be said to "aid" a body part or function. It "aids" in the regeneration of bone growth by providing a scaffolding to support bone remodeling. However, this framework appears to function more as a therapeutic device, which is a device that treats or cures an injury or disease and which is distinguished from a prosthetic device. Prior to 2010, Colorado exempted sales of therapeutic devices. This exemption applied to devices sold to "correct or treat" a human physical disability or surgically created abnormality.

Although prosthetic devices and therapeutic devices are similar, there are differences. See, e.g, Maine Instructional Bulletin No. 41, 12/06/2010 ("Orthopedic or therapeutic devices and appliances that do not replace a functioning part of the human body or do not correct physical malformity or malfunction are not prosthetic aids."); Code of Vt. Rules 1.9741(2)(E) Medical Exemption; Iowa Letter of Finding , 02/18/1992. For example, a cardiac pacemaker is generally characterized as a prosthetic device because it aids the heart function, but it is generally not characterized as a therapeutic device because it does not treat or cure the damaged heart. Conversely, Product here is generally designed to treat or cure an injury rather than provide a prosthetic in lieu of, or to aid in, the functioning of a non-functioning or missing body part. This distinction between therapeutic devices and prosthetics is important because the therapeutic device exemption was eliminated in 2010. Nevertheless, we need not rule

³ Department Regulation (39-)26-717.1. You can view this regulation at www.colorado.gov/revenue/tax > Tax Library > Rules and Regulations > Final Regulations > Sales and Use Taxes.

on whether the aid provided by the Product is the type contemplated by the prosthetic exemption because we find that the Product qualifies under the "materials furnished by a doctor" exemption, above.

Miscellaneous

This ruling applies only to sales and use taxes administered by the Department. The Department administers state and state-collected city and county sales taxes and special district sales and use taxes, but does not administer sales and use taxes for self-collected home rule cities and counties. You may wish to consult with local governments which administer their own sales or use taxes about the applicability of those taxes. Visit our web site at www.colorado.gov/revenue/tax for more information about state and local sales taxes.

This ruling is premised on the assumption that Company has completely and accurately disclosed all material facts. The Department reserves the right, among others, to independently evaluate Company's representations. This ruling is null and void if any such representation is incorrect and has a material bearing on the conclusions reached in this ruling. This ruling is subject to modification or revocation in accordance to Department Regulation 24-35-103.5.

Enclosed is a redacted version of this ruling. Pursuant to statute and regulation, this redacted version of the ruling will be made public within 60 days of the date of this letter. Please let me know in writing within that 60 day period whether you have any suggestions or concerns about this redacted version of the ruling.

Sincerely,

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