



COLORADO
Department of Revenue
Taxation Division

Office of Tax Policy
P.O. Box 17087
Denver, CO 80217-0087

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PLR-12-001 (amended)

February 19, 2014

XXXXXXXXXXXXXXXXXX
ATTN:XXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXX

Re: Private Letter Ruling

Dear XXXXXXXXXXXX,

The Department previously provided you a private letter ruling (PLR-12-001) dated February 14, 2012. The Department has revisited the issue of collagen gel discussed in your ruling and has removed such language from the ruling. This revision to the ruling does not affect the taxability of Company's Product. This private letter ruling supersedes our February 14, 2012 private letter ruling.

Issues

Is Company's sale of Product to hospitals and surgery centers in Colorado subject to Colorado 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 combination products that promote healing of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury.

The drug-device combination product ("Product") is an entirely synthetic product that assists in bone regeneration in certain surgeries and consists of two components. Product is supplied as a kit for single use only. The two primary components are combined and applied to the surgical site. One component is a highly porous, resorbable and osteoconductive scaffold that provides a framework for bone regeneration and promotes prevention of soft tissue infiltration and stabilization of blood clots. The other component stimulates the recruitment of various cell types.

Product is placed on gaps between bones where a surgeon is trying to achieve fusion. A scaffold for naturally occurring tissue (bone) regeneration is created by Product, which is gradually resorbed by the body and turned into bone. Company sells Product to hospitals and surgery clinics in Colorado. Product is pending approval by the Federal Drug Administration as a Class 3 Medical Device.

Discussion

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

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 service, (2) durable medical equipment and (3) prosthetic devices.²

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

Sales of materials furnished by a licensed provider as part of a professional service to patients are exempt from sales and use tax.³ In order to qualify for this exemption, the material must leave the licensed provider's office with the patient. For example, a catheter furnished by a doctor to drain fluid 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.⁴

Product is permanently absorbed by the bone tissue and, thus, leaves the doctor's office with the patient. In an analogous situation, we have determined that casts and splints, which are used to heal broken bones, fall within this exemption when they are furnished to the patient by physicians as part of a physician's professional service and the items leave the physician's office with 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. We caution, though, that not all materials furnished by a physician are exempt.

Finally, you state that Product is sold to hospitals and surgery centers as opposed to a licensed provider. It is these business entities, not the doctor, that purchase the materials which are ultimately used by the doctor as part of his or her professional service to the patient. We believe it would be an unwarranted limitation of this

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 generally, §39-26-717, C.R.S.

³ §39-26-717(1)(a), C.R.S.

⁴ For more information about this exemption, see, FYI Sales 68, which is available on our web site at www.taxcolorado.com and go to Tax Information > FYI Publications > Sales.

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, clinics or surgery centers, so long as the material is furnished by a licensed provider to a patient as part of their professional service. We rule that Company's sale of Product to hospitals and surgery centers is also exempt as a wholesale sale because we treat the transfer of materials to patient as an exempt retail sale, even if the price is not separately stated.

2. Durable Medical Equipment

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.⁵

Product does not appear to qualify for this exemption for two reasons. First, the Product is supplied as a kit for single use only and, therefore, cannot withstand repeated use. Second, Product is not worn outside the body. It is applied internally and permanently remains in the body.

3. Prosthetic Device

It is not clear whether the sale of Product qualifies under the exemption for prosthetic devices. The Department defines a prosthetic device as an artificial part which either aids or replaces a bodily function and which is designed, manufactured or adjusted to fit a particular individual.⁶ In some sense, Product replaces a body part by creating a framework over which existing bone grows to bridge gaps in 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 the framework over which existing bone grows. 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, appliances, or related accessories. This exemption applied to devices sold to "correct or treat" a human physical disability or surgically created abnormality and

⁵ **§39-26-717(2)(a), C.R.S.**

⁶ Department Rule (39-)26-717.1.

pursuant to a prescription. For example, a cardiac pacemaker is generally characterized as a prosthetic device because it aids the heart function, but not as a therapeutic device because it does not treat or cure the damaged heart.⁷ Conversely, the 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 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. Please note that 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.revenue.state.co.us 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,

Office of Tax Policy
Colorado Department of Revenue

⁷ 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.

STATE OF COLORADO

DEPARTMENT OF REVENUE

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John W. Hickenlooper
Governor

PLR-12-001

February 14, 2012

Barbara J. Brohl
Executive Director

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ATTN:XXXXXXXXXXXX
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Re: Private Letter Ruling

DearXXXXXXXXXXXX

Your firm submitted on behalf of "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

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Conclusion

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combined and applied to the surgical site. One component is a highly porous, resorbable and osteoconductive scaffold that provides a framework for bone regeneration and promotes prevention of soft tissue infiltration and stabilization of blood clots. The other component stimulates the recruitment of various cell types.

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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 service, (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 a professional service 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. For example, a catheter furnished by a doctor to drain fluid 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. For more information about this exemption, see, FYI Sales 68, which is available on our web site at: www.taxcolorado.com and go to Tax Information > FYI Publications > Sales.

Product is permanently absorbed by the bone tissue and, thus, leaves the doctor's office with the patient. In an analogous situation, we have determined that casts and splints, which are used to heal broken bones, fall within this exemption when they are furnished to the patient by physicians as part of a physician's professional service and the items leave the physician's office with 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.

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.

We caution, though, that not all materials furnished by a physician are exempt. For example, the item must be furnished to a "patient." A patient is one who seeks treatment of a medical issue. Thus, the Department has previously ruled that collagen gel, when used to eliminate smile lines, is not exempt because the product does not have a medical purpose and, therefore, is not furnished to a patient. There are, however, circumstances when collagen gel and other implants can serve a medical purpose and their sale is exempt. For example, breast implants after mastectomy surgery and cheek implants to replace lost facial tissue destroyed by an accident or melanoma skin cancer qualify for an exemption because they are furnished to a patient.

Finally, you state that Product is sold to hospitals and surgery centers as opposed to a licensed provider. It is these business entities, not the doctor, that purchase the materials which are ultimately used by the doctor as part of his or her professional service to the patient. 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, clinics or surgery centers, so long as the material is furnished by a licensed provider to a patient as part of their professional service. We rule that Company's sale of Product to hospitals and surgery centers is also exempt as a wholesale sale because we treat the transfer of materials to patient as an exempt retail sale, even if the price is not separately stated.

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§ 39-26-717(2)(a), C.R.S. Product does not appear to qualify for this exemption for two reasons. First, the Product is supplied as a kit for single use only and, therefore, cannot withstand repeated use. Second, Product is not worn outside the body. It is applied internally and permanently remains in the body.

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Product replaces a body part by creating a framework over which existing bone grows to bridge gaps in 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.

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Sincerely,

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