06-021

REQUEST LETTER

October 9, 2006

TP REPRESENTATIVE
ADDRESS

Dear TP REPRESENTATIVE:

My client is a manufacturer and retailer of a medical birth control device. This medical device is a new form of permanent birth control which is designed to provide an alternative to incisional methods of tubal ligation for women seeking permanent contraception.

The permanent birth control device is surgically implanted

The permanent birth control system consists of micro-insert, a disposable delivery system, and a disposal split introducer. The micro-insert consists of a stainless steel inner coil, a nitinol. Superelastic outer coil, and polyethelene terephthalate (PET) fibers. The disposable delivery system consists of a single-handed ergonomic handle which contains a delivery wire, release catheter, and delivery catheter.

Using a hysteroscope, a gynecologist places one micro-insert in the proximal section of each fallopian tube lumen. When the micro-insert expands upon release, it remains anchored in the fallopian tube and results in permanent birth control.

The birth control device has received Federal Food and Drug Administration Approval.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has approved the device for commercial distribution under the following conditions:

1. The sale, distribution, and use of this device is restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of sections 520(e) of the Federal Food, Drug, and Cosmetic Act.
2. To ensure the safe and effective use of the device, professional labeling must specify the training requirement of practitioners who may use the device and
3. The sales, distribution, and use must not violate sections 502(q) and (r) of the act

Important

- Caution: Federal law restricts this device to sale by or in the order of a physician. This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instruction for use and in the Physical Training Manual, and have successfully completed the training program. Completion of the Training Program includes preceptoring the product in placement until competency is established, which is typically expected to be achieved in 5 cases.

Important

- The micro-inserts should **NOT** be relied on for contraception until the patient has undergone a hysterosalpingogram (HSG) 3 months after micro-insert placement, which demonstrates **both** bilateral tubal occlusion **and** satisfactory location of the micro-inserts.
- If micro-inserts cannot be placed bilaterally, then the patient should not rely on this method of sterilization. This product has not been proven to be effective when it is placed unilaterally.
- This product is intended to prevent pregnancy. It does not Protect against either HIV infection or other sexually transmitted diseases.

Women chose permanent birth control for health reasons

According to the Center for Disease Control and Prevention (CDC), an unintended pregnancy is a significant public health issue that affects not only the woman's health but also the health of the newborn infant and society as a whole. Many women are not healthy enough to risk an unintended pregnancy and may develop a serious disease as a result. For example, some pregnant women are vulnerable to detrimental health conditions such as hypertension, diabetes and heart disease.

More than one in three pregnant women in the U.S. develop a pregnancy-related complication and two or three women die every day from these pregnancy related complications. The risks of pregnancy related deaths die after the age of 35. By the age of 40, pregnancy-related risks for women rise as much as 50 times higher than women in their twenties. Although teenagers have the highest rate of unintended pregnancy, the second highest rate is found in women aged 40-44.

Summary

It is well documented that an unintended pregnancy for a woman is a significant health issue. My client's product provides a safe and reliable alternative for women to achieve permanent contraception in order to protect their health and wellbeing. My client's product is restricted to prescription used by trained practitioners for permanent surgical implantation in the women's fallopian tube and this birth control procedure is not reversible. Since this procedure is used to achieve permanent birth control, the product will be used by older women to prevent an unwanted pregnancy and the related health complications.

Taxability of the permanent birth control device

Given that my client has nexus with your state and that my client's customers are located in your state, are the sales of the permanent birth control device described above subject to sales or use tax in your state?

Sincerely,

NAME
ADDRESS

RESPONSE LETTER

October 5, 2007

NAME
ADDRESS

Re: Private Letter Ruling 06-021
Applicability of Sales Tax Exemptions to surgically implanted permanent birth control devices

Dear NAME,

This letter is in response to your October 9, 2006 request for tax guidance. This letter ruling is an interpretation and application of the tax law to the facts presented in your letter. It is not a statement of broad Tax Commission policy. If the facts of your client's situation differ from the facts described in this letter ruling, please let me know so we can assure a more accurate response to your client's circumstances.

Facts

Your client manufactures and makes retail sales of a medical birth control device. The device is a form of permanent birth control. It is surgically implanted in the proximal section of each fallopian tube lumen, where it remains anchored after implantation. It is an alternative to tubal ligation for women seeking permanent contraception.

The Federal Food and Drug Administration has approved the device for commercial distribution under the following conditions:

1. The sale, distribution, and use of this device is restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of sections 520(e) of the Federal Food, Drug, and Cosmetic Act.

2. To ensure the safe and effective use of the device, professional labeling must specify the training requirement of practitioners who may use the device and

3. The sales, distribution, and use must not violate sections 502(q) and (r) of the act.

The following labels apparently appear on the product:

Important

- Caution: Federal law restricts this device to sale by or in the order of a physician. This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instruction for use and in the Physical Training Manual, and have successfully completed the training program. Completion of the Training Program includes preceptoring the product in placement until competency is established, which is typically expected to be achieved in 5 cases.

Important

- The micro-inserts should **NOT** be relied on for contraception until the patient has undergone a hysterosalpingogram (HSG) 3 months after micro-insert placement, which demonstrates **both** bilateral tubal occlusion **and** satisfactory location of the micro-inserts.
- If micro-inserts cannot be placed bilaterally, then the patient should not rely on this method of sterilization. This product has not been proven to be effective when it is placed unilaterally.
- This product is intended to prevent pregnancy. It does not Protect against either HIV infection or other sexually transmitted diseases.

Analysis

Utah Code Annotated §59-12-103 imposes a sales tax on retail sales of tangible personal property, unless otherwise exempt. Tangible personal property is defined as any personal property that may be seen, weighed, measured, felt, touched, or is in any other manner perceptible to the senses. See Utah Code Ann. §59-12-102(97). The device in question is clearly tangible personal property within the meaning of this definition and, accordingly, a tax would be due on the sale of the device unless there is a specific exemption.

There are three possible exemptions that could apply: an exemption for drugs, provided in Utah Code Ann. §59-12-104(10), an exemption for durable medical equipment provided in Utah Code Ann. §59-12-104(36), and an exemption for prosthetic devices provided in Utah Code Ann. §59-12-104(55).

Drugs. Section 59-12-104(10) provides an exemption for certain sales of drugs, as follows:

> *(10) (a) amounts paid for an item described in Subsection (10)(b) if:*
> *(i) the item is intended for human use; and*
> *(ii) (A) a prescription was issued for the item; or*
> *(B) the item was purchased by a hospital or other medical facility; and*
> *(b) (i) Subsection (10)(a) applies to:*
> *(A) a drug;*
> *(B) a syringe; or*

(C) a stoma supply . . . .

Utah Code Section 59-12-102 (29) defines "drug" as follows:

(a) "Drug" means a compound, substance, or preparation, or a component of a compound, substance, or preparation that is:
(i) recognized in:
(A) the official United States Pharmacopoeia;
(B) the official Homeopathic Pharmacopoeia of the United States;
(C) the official National Formulary; or
(D) a supplement to a publication listed in Subsections (29)(a)(i)(A) through (C);
(ii) intended for use in the:
(A) diagnosis of disease;
(B) cure of disease;
(C) mitigation of disease;
(D) treatment of disease; or
(E) prevention of disease; or
(iii) intended to affect:
(A) the structure of the body; or
(B) any function of the body.
(b) "Drug" does not include:
(i) food and food ingredients;
(ii) a dietary supplement;
(iii) an alcoholic beverage; or
(iv) a prosthetic device.

It does not appear that the device is a "compound, substance, or preparation" recognized in any of the publications mentioned in the definition. Thus, although the device may be intended for the mitigation or prevention of disease and is intended to affect a function of the body, it is not a "drug" under Utah law.

Durable medical equipment. Utah Code Section 59-12-104(36) allows a sales tax exemption for sales of "durable medical equipment" as follows:

(36) sales or rentals of durable medical equipment if:
(a) a person presents a prescription for the durable medical equipment; and
(b) the durable medical equipment is used for home use only. . . .

"Durable medical equipment" is defined in Utah Code Ann. §59-12-102(30) as follows:

(30) (a) Except as provided in Subsection (30)(c), "durable medical equipment" means equipment that:
(i) can withstand repeated use;
(ii) is primarily and customarily used to serve a medical purpose;

(iii) generally is not useful to a person in the absence of illness or injury; and

(iv) is not worn in or on the body.

(b) "Durable medical equipment" includes parts used in the repair or replacement of the equipment described in Subsection (30)(a).

(c) Notwithstanding Subsection (30)(a), "durable medical equipment" does not include mobility enhancing equipment.

Because the device is clearly worn "in or on the body" of the patient, it does not qualify as "durable medical equipment."

Prosthetic device. Finally, Utah Code Ann. §59-12-104(55) allows a sales tax exemption for sales of "prosthetic devices" as follows:

(55) sales of a prosthetic device:

(a) for use on or in a human;

(b) for which a prescription is issued; and

(c) to a person that presents a prescription for the prosthetic device. . . .

"Prosthetic device" is defined in Utah Code Ann. §59-12-102(69) as follows:

(a) "Prosthetic device" means a device that is worn on or in the body to:

(i) artificially replace a missing portion of the body;

(ii) prevent or correct a physical deformity or physical malfunction; or

(iii) support a weak or deformed portion of the body.

(b) "Prosthetic device" includes:

(i) parts used in the repairs or renovation of a prosthetic device; or

(ii) replacement parts for a prosthetic device.

(c) "Prosthetic device" does not include:

(i) corrective eyeglasses;

(ii) contact lenses;

(iii) hearing aids; or

(iv) dental prostheses.

The device is not a "prosthetic device," as defined in 59-12-102(69), because it does not replace a missing portion of the body, prevent or correct a physical deformity or physical malfunction, or support a weak or deformed portion of the body.

"Even though taxing statutes should generally be construed favorable to the taxpayer and strictly against the taxing authority, the reverse is true of exemptions. Statutes which provide for exemptions should be strictly construed, and one who so claims has the burden of showing his entitlement to the exemption. Parson Asphalt Prods., Inc. v. State Tax Comm'n, HREF="http://198.187.128.12/utahextranet/lpext.dll?f=FifLink&t=document-frame.htm&l=jump&iid=4c4e777f.15ec5e70.0.0&nid=4114d#JD_p2d617397" MACROBUTTON HtmlResAnchor 617 P.2d 397, 398 (Utah 1980)."

Ruling

The device is tangible personal property, as defined in 59-12-102(97)(a). The transfer of the title to the device for consideration is a sale under 59-12-102 (83) (a). It is similar to the sale of artificial limbs, which has been held to be the sale of tangible personal property. See McKendrick v. State Tax Comm'n, 9 Utah 2d 418, 347 P.2d 177 (1959). It appears to be a retail sale, as defined by 59-12-102(81). As such, it is subject to sales tax under 59-12-103(1) unless it qualifies for an exemption. Possible exemptions are found in 59-12-104. Exemptions are to be strictly construed, with the burden on the one claiming an exemption to show one's entitlement to the exemption. Parson, supra.

The device is not a drug, as defined in 59-12-102 (29) because it is not a "compound, substance, or preparation" recognized in the official publications outlined in the statute. It is not durable medical equipment, as defined in 59-12-102 (30), because it is "worn on or in the body." It is not a prosthetic device, as defined in 59-12-102(69), because it does not replace a missing portion of the body; prevent or correct a physical deformity or physical malfunction; or support a weak or deformed portion of the body. Thus, under the circumstances outlined in your request, the sale of the device does not qualify for an exemption under these provisions.

Our analysis is based on the assumption that the facts as you have represented them are correct. Should the conditions or circumstances be other than as you have represented, our conclusions may differ. If you feel we have misunderstood the facts as you have presented them, or if you have additional facts that you feel may alter our position, or you have any other questions, please contact us.

For the Commission,

Marc B. Johnson
Commissioner

MBJ/SR
PLR 06-021