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PRIVATE TAXPAYER RULING LR03-014

December 11, 2003

This private taxpayer ruling is in response to your letters dated April 22, 2003, as updated on May 8, 2003 and June 11, 2003, in which you requested private taxpayer rulings on behalf of ... ("Taxpayer"). Your private taxpayer ruling requests relate to whether the transaction privilege tax and use tax exemptions under Arizona Revised Statutes ("A.R.S.") §§ 42-5061(A)(9) and 42-5159(A)(17) are available to Taxpayer with respect to its sales of breast implants, tissue expanders, and stomach bands to Arizona customers.

Statement of Facts:

Your letters dated April 22, 2003 explain that Taxpayer is a ... headquartered corporation, which is primarily engaged in the manufacture and sale of medically related products including breast implants, tissue expanders, and adjustable stomach band systems.

Your April 22, 2003 letters present the facts relating to each of these specific products as follows:

Breast Implants

[Taxpayer's] breast implants are purchased by medical service providers, surgeons who perform the breast implant procedure or the health facilities in which the procedure is performed. The products are not sold directly to patients ... but are prescribed for the use of patients and surgically put in place by qualified medical professional[s] in approved medical facilities.

The breasts are medically considered to be internal organs. The breasts are a group of components, not merely the mammary glands. The breast[s] encompass the entire upper thoracic portion of the body. Breasts are composed of fatty or adipose tissue, glandular or mammary tissue, ligaments and underlying muscles, all overlying the upper skeleton including the ribcage. Asymmetry and other breast conditions could be caused by abnormalities of the fatty tissue, the glandular tissue, or both....

Breast implants are used in a number of surgical procedures. In cancer treatment, after a mastectomy, doctors frequently prescribe breast reconstruction involving an implant to mitigate the disfiguring effects of the

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[surgery]. Post-mastectomy reconstruction is often necessary even when the entire breast was not removed. Reconstructive surgery may also be performed after subcutaneous mastectomies for fibrocystic breast disease. Breast implants are also used in breast augmentation surgery. Augmentation is a surgical procedure to modify the size or shape of breasts. One medical condition frequently requiring breast augmentation is congenital asymmetry of the breasts. Another medical condition requiring breast augmentation is ptosis or sag following childrearing or weight loss. Surgical placement of the breast implant is necessary to support reshaped tissue, to accommodate surgical corrections to other organs or bodily structures such as lymph and muscle tissues underlying the breast.

.... The breast implant consists of a silicone bag filled with an approved solution. The implants are designed to minimize leakage and rupture. The implant is placed surgically into a breast. Incisions are made either through the nipple and aureola, through the armpit, or through the bottom of the breast. The surgeon may elect to place the implant either over or under the underlying muscle. In either case, a pocket is formed, the implant inserted and the breast sutured closed.

Tissue Expanders

[Taxpayer's] tissue expanders are purchased by medical service providers, surgeons who perform the breast implant placement and other reconstructive procedures or the health facilities in which the procedures are performed. The products are not sold directly to patients ... but are prescribed for the use of patients and surgically put in place by qualified medical professionals in approved medical facilities.

Tissue expanders are used in an essential preliminary procedure in some reconstructive surgery. Often, due to scarring or other conditions, the site in the human body for reconstructive surgery must be modified to create suitable conditions for the final reconstructive surgical procedure. Tissue expanders may be used in breast reconstruction surgery to establish a pocket for insertion of a breast implant. Tissue expanders are also used in the repair of catastrophic burns or wounds to stretch the adjacent skin to create a flap to cover the burn or wound.

The tissue expander is a silastic bag with a self-sealing injection port. The tissue expander is surgically implanted under the skin in a pocket made between the skin and muscle tissue. After the expander is inserted into the pocket, the incision is closed with nonabsorbable sutures. The device is then inflated with just enough saline solution to expand and fill the dead space in the surgically established pocket. After the expander is implanted, sterile

techniques are used to access the injection port of the implanted expander. Every third to seventh day the tissue expander is gradually enlarged by addition of incremental amounts of saline solution. The expander is left inside the patient and gradually expanded for the period of time required to achieve the necessary stretching of the skin to accommodate a permanent breast implant or establish a skin flap to cover a burn or wound. The expander process generally requires several months and may take in excess of a year to complete.

Stomach Band Systems

[Taxpayer's stomach band] is used for treatment of morbid obesity. It has been used internationally for a number of years and on June 5, 2001 was approved by the Food and Drug Administration [(“FDA”)] for use in the United States as a medical device. The components of the [stomach band system] are purchased by medical service providers, surgeons who perform the [stomach band] placement procedure or the health facilities in which the procedure is performed. The product is not sold directly to patients ... but is prescribed for the use of patients and surgically put in place by qualified medical professional[s] in approved medical facilities....

Patients suffering from morbid obesity who have not responded to conservative weight reduction alternatives, such as diet, exercise and behavior modification program, may be candidates for a surgical procedure to address their condition. In these surgical procedures, a dysfunctional stomach, which allows chronic excessive food intake, is replaced with a permanently modified stomach, which is smaller and functions properly to prevent excessive food intake for the individual.

[The stomach band system] replaces the larger capacity stomach, which contributed to a patient's morbid obesity, with a smaller capacity stomach. The [stomach band] is an inflatable band that is placed around the upper stomach and tightened by inflation with saline solution to form a small gastric pouch, which limits food consumption and creates an earlier feeling of satiety or fullness than occurs in the unrestricted stomach. The [stomach band] is implanted by laparoscopic “keyhole” surgery and is connected by tubing to an access port needle to introduce or remove saline solution to adjust inflation of the [stomach band] over time by either tightening or loosening to change the size of the gastric pouch for the needs of the individual patient. The calibration tube includes an integral balloon that is used to establish gastric pouch dimensions and [stomach band] location during placement. The [stomach band] and access port are intended to remain permanently implanted (i.e., removal is not anticipated) so that the beneficial effects from weight loss are maintained. All the components of the [stomach band

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system] are necessary for the proper functioning of the implanted [stomach band].

Issues:

1. Is Taxpayer's sale of breast implants exempt from transaction privilege and use tax under A.R.S. §§ 42-5061(A)(9) and 42-5159(A)(17)?
2. Is Taxpayer's sale of tissue expanders exempt from transaction privilege and use tax under A.R.S. §§ 42-5061(A)(9) and 42-5159(A)(17)?
3. Is Taxpayer's sale of stomach bands exempt from transaction privilege and use tax under A.R.S. §§ 42-5061(A)(9) and 42-5159(A)(17)?

Your Position:

You have stated your position as follows:

1. With respect to ***breast implants***:

[Taxpayer's] breast implant qualifies as a "prosthetic appliance" exempt from tax under ARS 42-5061.A.9 and ARS 42-5159.A.17. Breast implants always support or take the place of or replace natural tissue which is missing, whether due to disease, surgery, malformation or simply inadequate or improper growth. Reconstruction or augmentation by a breast implant to mitigate post-surgical disfigurement, or for treatment of congenital asymmetry of the breasts or for ptosis or sag, is within the scope of the statute and [rules].... A device is a prosthetic appliance whether the tissue or organ replaced was once present, but lost due to accident, surgery or disease, or was never present....

[Taxpayer's] breast implants are prescribed by a licensed professional and always "take the place of" a part of the body which is missing and "replace" natural tissue....

You conclude:

A breast implant is an artificial device that is necessary to support or take place of a part of the body and replace natural tissue which is missing, whether due to disease, surgery, malformation or simply inadequate growth. A breast implant: (1) places the breast tissue again, or restores the breast to a former place, position or condition, or (2) takes the place of the missing

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breast tissue, or serves as a substitute for the missing breast tissue, or (3) is put in the place of the missing breast tissue, or provides a substitute for the missing breast tissue, or (4) fills the place of the missing breast tissue.

[Taxpayer's] breast implant products are within the exemptions provided for "prosthetic appliances." Accordingly, sales of these medical products are not subject to the retail business transaction privilege tax and purchasers of these products are not subject to the use tax.... [Taxpayer's] sales of the breast implants to medical service providers should be exempt from Arizona transaction privilege and use taxes under ARS 42-5061.A.9 and ARS 42-5159.A.17.

2. With respect to *tissue expanders*:

[Taxpayer's] tissue expander products qualify as a "prosthetic appliance" exempt from tax under ARS § 42-5061.A.9 and ARS § 42-5159.A.17.... The exemption is based on the use of the product in accordance with a prescription from a qualified professional and reaches all the components necessary and essential to the function of the prosthetic appliance.... A tissue expander literally "supports" the tissue overlying a site in the human body or reconstructive surgery. Moreover, the tissue expander is "necessary" to the reconstructive surgical procedure to place a breast implant or remedy the site of a wound or deformity....

Reconstructive surgery always replaces natural tissue which is missing due to disease, surgery, malformation or simply inadequate growth. For some breast implant procedures, tissue expanders are necessary and essential to prepare the breast tissue for the ultimate placement of the implant which will replace missing natural tissue. Since breast implants are prosthetic devices, and the expanders are necessary and essential to the implant procedure, the expanders are also within the scope of the prosthetic appliance exemption. Similarly, tissue expanders required to establish a skin flap to cover the site of other reconstructive surgeries are necessary and essential to that process of replacing a missing portion of the human body....

You conclude:

[Taxpayer's] tissue expander products are within the exemptions provided for "prosthetic appliances." Accordingly, sales of these medical products are not subject to the retail business transaction privilege tax and purchasers of these products are not subject to the use tax.... [Taxpayer's] sales of the ... tissue expanders to medical service providers should be exempt from Arizona transaction privilege and use tax under ARS 42-5061.A.9 and ARS 42-5159.A.17.

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3. With respect to **stomach band systems**:

[Taxpayer's stomach band system] product qualifies as a "prosthetic appliance" exempt from tax under ARS § 42-5061.A.9 and ARS § 42-5159.A.17. The [stomach band] replaces the dysfunctional larger capacity stomach which contributed to a patient's morbid obesity with a functional smaller capacity stomach. All the components of the [stomach band system] are necessary and essential to the full function of the appliance and, therefore, these components together constitute a prosthetic appliance exempt from the transaction privilege and use taxes.

[Taxpayer's stomach band system] product is within the exemptions provided for "prosthetic appliances." Accordingly, sales of these medical products are not subject to the retail business transaction privilege tax and purchasers of these products are not subject to the use tax.... [Taxpayer's] sales of the [stomach band] to medical service providers should be exempt from Arizona transaction privilege and use taxes under ARS 42-5061.A.9 and ARS 42-5159.A.17.

Conclusion and Ruling:

On the basis of the information provided, Taxpayer's sale of its products to Arizona customers is subject to transaction privilege tax under A.R.S. § 42-5061 or use tax under A.R.S. § 42-5155 unless specifically exempt. The statutory definitions of "prosthetic appliance" for purposes of the exemptions under A.R.S. §§ 42-5061(A)(9) and 42-5159(A)(17) indicate a prerequisite absence of a body part or a body function. Breast implants that are used solely to augment or reshape an existing, completely-formed breast; tissue expanders, which act as temporary tools not as permanent body parts; and stomach band systems, which cover an existing, completed stomach, do not partially or fully take the place of an absent body part. When the related body part is present (as kidneys are present in a dialysis scenario), the only option for prosthetic status under the statutory definitions is that such device supports or takes the place of a function of a body part. Breast implants, which inhibit the functions of a natural breast; tissue expanders, which perform a non-bodily function; and stomach band systems, which constrict an existing, fully-operational stomach, do not substitute for functions of a human body part. Therefore, breast implants that augment an existing breast, tissue expanders, and stomach band systems do not constitute "prosthetic appliances."

The following ruling is given based on the facts presented in your requests.

The Department rules that Taxpayer's sales of reconstructive breast implants or implants that repair congenitally *unformed* breasts will qualify for the exemptions under A.R.S. §§ 42-5061(A)(9) or 42-5159(A)(17) if such implants are prescribed or recommended by a

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proper health professional. Sales of breast implants used only for augmentation or reforming purposes do not qualify for the exemptions under A.R.S. §§ 42-5061(A)(9) or 42-5159(A)(17).

The Department further rules that Taxpayer's sales of tissue expanders, stomach bands, and stomach band systems do not qualify for the exemptions under A.R.S. §§ 42-5061(A)(9) or 42-5159(A)(17).

The conclusions in this private taxpayer ruling do not extend beyond the facts presented in your letters dated April 22, 2003, as updated on May 8, 2003 and June 11, 2003.

This response is a private taxpayer ruling and the determinations herein are based solely on the facts provided in your request. The determinations are subject to change should the facts prove to be different on audit. If it is determined that undisclosed facts were substantial or material to the Department's making of an accurate determination, this taxpayer ruling shall be null and void. Further, the determination is subject to future change depending on changes in statutes, administrative rules, case law or notification of a different Department position.

The determinations in this private taxpayer ruling are applicable only to the taxpayer requesting the ruling and may not be relied upon, cited nor introduced into evidence in any proceeding by a taxpayer other than the taxpayer who has received the private taxpayer ruling.