

New York State Department of Taxation and Finance
Office of Counsel
Advisory Opinion Unit

TSB-A-09(16)S
Sales Tax
April 17, 2009

STATE OF NEW YORK
COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION

PETITION NO. S090223A

On February 23, 2009, the Department of Taxation and Finance received a Petition for Advisory Opinion from [REDACTED], [REDACTED].

The issue raised by [REDACTED] ("Petitioner") is whether its sales of biological soft tissue products described below to hospitals and medical service providers are subject to New York State sales and use taxes.

It is concluded that Petitioner's products, [REDACTED] and [REDACTED], qualify as prosthetic aids under Section 1115(a)(4) of the Tax Law and are therefore exempt from New York State sales and use taxes.

Facts

Petitioner is a processor and marketer of biological soft tissue products made from human and animal tissues. Petitioner's products include [REDACTED], a human tissue product used in plastic reconstructive, general surgical, burn and periodontal procedures, and [REDACTED], an animal tissue product used in plastic reconstructive and general surgical procedures.

[REDACTED] is derived from donated human skin tissue and has been classified as banked human tissue by the Food and Drug Administration (FDA). It is predominantly used as a subcutaneous implant for the replacement of soft tissue in reconstructive surgical procedures in various areas of the body. [REDACTED] is porcine dermis (pig skin) that has been processed to form a tissue matrix. It is regulated by the FDA as a medical device and is used as a soft tissue patch and for surgical repair of damaged or ruptured soft tissue membranes.

Petitioner's products are sold to hospitals and medical service providers and used in procedures such as: abdominal wall reconstruction, hernia repair, post-mastectomy breast reconstruction, trauma or previous surgery repair, tumor resection, ENT/head and neck reconstruction, burn graft, wound coverage, mucosal grafts, oral resurfacing, and rotary cuff tissue repair. Petitioner's products are incorporated into the patients' existing soft tissues, but remain separately identifiable after implantation.

Opinion

Section 1105(a) of the Tax Law imposes a tax on "[t]he receipts from every retail sale of tangible personal property, except as otherwise provided in this article."

Section 1115(a)(3) of the Tax Law exempts from the sales tax imposed by section 1105(a) and from the compensating use tax imposed under section 1110 medical equipment and supplies required for use in the cure, mitigation, treatment or prevention of illnesses or diseases in human beings or to correct or alleviate physical incapacity, unless the medical equipment or supplies are "purchased at retail for use in performing medical and similar services for compensation." Section 1115(a)(4) of the Tax Law exempts from tax "[p]rosthetic aids,

hearing aids, eyeglasses and artificial devices and component parts thereof purchased to correct or alleviate physical incapacity in human beings.”

Section 528.5 of the Sales and Use Tax Regulations provides, in part:

(a) *Exemption*. Prosthetic aids, hearing aids, eyeglasses and artificial devices and component parts thereof, purchased to correct or alleviate physical incapacity in human beings are exempt from the tax.

(b) *Qualifications*. (1) In order to qualify as a prosthetic aid, a hearing aid, eyeglasses or an artificial device, the property must either completely or partially replace a missing body part or the function of a permanently inoperative or permanently malfunctioning body part and must be primarily and customarily used for such purposes and not be generally useful in the absence of illness, injury or physical incapacity.

The function of the product is key in determining whether it should be classified as *medical equipment*, which is taxable when sold for use in performing medical or similar services for compensation, or as a *prosthetic aid*, which is exempt from sales tax under section 1115(a)(4) of the Tax Law, whether or not it will be used in performing medical services for compensation. See Comprehensive Dialysis Center of WNY, Inc., Adv Op Comm T&F, August 4, 1998. See also Publication 822 (6/01), *Taxable Status of Medical Equipment and Supplies, Prosthetic Devices, and Related Items*.

To qualify as a prosthetic aid, the tangible personal property must either completely or partially replace a missing body part or the function of a permanently inoperative or permanently malfunctioning body part, and must be primarily and customarily used for such purposes and not be generally useful in the absence of illness, injury or physical incapacity. See Section 528.5(b)(1) of the Sales and Use Tax Regulations.

In Orthovita, Inc., Adv Op Comm T&F, June 25, 2002, TSB-A-02(14)S, it was concluded that a synthetic bone filler which replaced a patient’s hard outer bone structure satisfied the prosthetic aid qualifications set forth under Section 528.5 because it either *completely or partially replaces a missing body part* (emphasis added). However, a second type of bone filler was found not to qualify as a prosthetic aid. This bone filler merely repaired the porous inner core of the bone, and after implantation became absorbed by the body and later replaced by bone. Thus, it did not completely or partially replace a missing body part because it did not remain in the body.

The function of Petitioner’s [REDACTED] and [REDACTED] products is to replace soft tissues that are missing, permanently inoperative, or permanently malfunctioning. These products either *completely or partially replace the patient’s skin or the function of the skin*. As described by Petitioner, these “products are incorporated into the patients [sic] existing soft tissues, [however,] they remain separately identifiable after implantation” in the body. Petition at 2.

In Technical Services Bureau Memorandum entitled Sales and Compensating Use Tax Treatment of Products Used in the Restorations of Teeth, March 20, 2006, TSB-M-06(5)S, dental devices such as implants, dentures, bridges, full and partial crowns, onlays, and inlays were found to be prosthetic devices exempt from sales tax because they completely or partially replaced missing teeth or the functions of permanently inoperative or permanently malfunctioning teeth. However, because of the regulatory requirement that prosthetic aids be primarily and customarily used for such purposes and not generally useful in the absence of illness, injury, or physical incapacity, dental devices that are cosmetic in nature, such as laminate veneers, decorative caps, and specialty or jewelry teeth, were determined not to qualify as exempt prosthetic aids.

By contrast, the [REDACTED] and [REDACTED] products are used to repair defects resulting from trauma, previous surgery, general failure of tissue, infection, tumor resection, and damaged or ruptured soft tissue membranes. These products are not cosmetic in nature. Accordingly, they satisfy the regulatory requirements that they be primarily and customarily used to completely or partially replace a patient's skin or the function of the skin and not be generally useful in the absence of illness, injury or physical incapacity.

Therefore, the [REDACTED] and [REDACTED] products qualify as prosthetic aids under Section 1115(a)(4) of the Tax Law and their sales to purchasers performing medical services for compensation are exempt.

DATED: April 17, 2009

/S/

Jonathan Pessen
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NOTE: An Advisory Opinion is issued at the request of a person or entity. It is limited to the facts set forth therein and is binding on the Department only with respect to the person or entity to whom it is issued and only if the person or entity fully and accurately describes all relevant facts. An Advisory Opinion is based on the law, regulations, and Department policies in effect as of the date the Opinion is issued or for the specific time period at issue in the Opinion.