STATE OF NEW YORK COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION PETITION NO. S000727A

On July 27, 2000, the Department of Taxation and Finance received a Petition for Advisory Opinion from Orthovita, Inc., 45 Great Valley Pkwy, Malvern, PA 19355. Petitioner, Orthovita, Inc., furnished additional information with respect to the Petition on August 15, 2000.

The issue raised by Petitioner is whether its sales of Vitoss and Cortoss, which are synthetic bone void fillers described below, to hospitals and physicians are exempt from New York State and local sales and use taxes as prosthetic aids.

Petitioner submits the following facts as the basis for this Advisory Opinion.

Vitoss and Cortoss are synthetic bone void fillers which are regulated as medical devices. The products are surgically implanted to take the place of weakened and diseased bone. Vitoss and Cortoss, when surgically implanted, are meant to take the place of a bone defect caused by illness or trauma. An example of a bone defect would be a hole caused by the removal of a tumor.

Vitoss is designed to repair the porous inner core of bone. Vitoss, when surgically implanted in a bone defect, serves as a template to guide bone regeneration throughout the defect. Vitoss, through absorption into the body and bone, after time is replaced by bone. Vitoss is formed as either a scaffold matrix or in an injectable form. The matrix version is a porous, spongy material that is sold in the form of small (9 x 23 mm) blocks or "morsels" (1-4 mm in diameter), which are shaped during a surgical procedure as necessary to fill a defect.

Cortoss is designed to replace the hard outer bone structure. Cortoss is manufactured in an injectable form or as a putty. Unlike Vitoss, Cortoss is not replaced by bone but acts as a permanent bone filler.

Applicable Law and Regulations

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

Section 1115(a) of the Tax Law provides, in part:

Receipts from the following shall be exempt from the tax on retail sales imposed under subdivision (a) of section eleven hundred five and the compensating use tax imposed under section eleven hundred ten:

*

*

(3) Drugs and medicines intended for use, internally or externally, in the cure, mitigation, treatment or prevention of illnesses or diseases in human beings, medical equipment (including component parts thereof) and supplies required for such use or to correct or alleviate physical incapacity, and products consumed by humans for the preservation of health but not including cosmetics or toilet articles notwithstanding the presence of medicinal ingredients therein or medical equipment (including component parts thereof) and supplies, other than such drugs and medicines, purchased at retail for use in performing medical and similar services for compensation.

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

Section 528.4(a) of the Sales and Use Tax Regulations provides, in part:

Exemption. (1) Drugs and medicines intended for the use, internally or externally in the cure, mitigation, treatment or prevention of illnesses or diseases in human beings, medical equipment (including component parts thereof) and supplies required for such use or to correct or alleviate physical incapacity, and products consumed by humans for the preservation of health are exempt.

* * *

(e) Medical equipment. (1) Medical equipment means machinery, apparatus and other devices (other than prosthetic aids, hearing aids, eyeglasses and artificial devices which qualify for exemption under section 1115(a) (4) of the Tax Law), which are intended for use in the cure, mitigation, treatment or prevention of illnesses or diseases or the correction or alleviation of physical incapacity in human beings.

(2) To qualify, such equipment must be primarily and customarily used for medical purposes and not be generally useful in the absence of illness, injury or physical incapacity.

* * *

(g) Supplies. (1) Supplies used in the cure, mitigation, treatment or prevention of illnesses or diseases or for the correction and alleviation of physical incapacity are exempt.

*

*

(2) Medical supplies are not exempt if purchased by a person performing medical or similar services for compensation. (See subdivision (h) of this section.)

(h) Taxable medical equipment and supplies. (1) Medical equipment and supplies purchased for use in performing medical or similar services for compensation are not exempt from tax.

* * *

(2) Medical services for human beings include but are not limited to the practices of medicine, dentistry, physical therapy, chiropractic, nursing, podiatry, optometry and radiology, whether performed by a private practitioner, clinical laboratory, hospital, nursing home, ambulance service, clinic, or health maintenance facilities.

(3) It is immaterial whether the compensation is paid to the practitioner or institution by the patient or another source.

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

Prosthetic aids. (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.

Opinion

Vitoss is designed to repair the porous inner core of bone. Vitoss, when surgically implanted in a bone defect, serves as a template to guide bone regeneration. While performing this function, Vitoss is absorbed by the body and is replaced by bone. In <u>Alcon Surgical, Inc.</u>, Adv Op Comm T&F, May 27, 1992, TSB-A-92(43)S, it was concluded that the corneal shield used to accelerate healing in postoperative or traumatic corneal injuries, refractive surgical procedures and other corneal conditions, which subsequently dissolves in the eye, is a medical supply for purposes of the exemption contained in Section 1115(a)(3) of the Tax Law since it is a therapeutic device similar

to ophthalmic suture materials. John O. Butler Company, Adv Op Comm T&F, November 4, 1992, TSB-A-92(77)S, concluded that a bio-medical device which is fastened around the neck of a tooth to guide in the regeneration of periodontal tissues lost due to disease and which later dissolves in the patient's mouth is not a prosthetic aid. Rather, it is a medical supply for purposes of the exemption contained in Section 1115(a)(3) of the Tax Law. Like the items at issue in Alcon Surgical, Inc., supra, and John O. Butler Company, supra, Vitoss does not remain in the body. Vitoss does not completely or partially replace a missing body part or replace the function of a permanently inoperative or permanently malfunctioning body part within the meaning and intent of Section 528.5 of the Sales and Use Tax Regulations. Vitoss, therefore, does not qualify as a prosthetic aid under Section 1115(a)(4) of the Tax Law. Rather, Vitoss is a medical supply for purposes of the exemption contained in Section 1115(a)(3) of the Tax Law. Accordingly, the receipts from the sale of Vitoss to persons purchasing the product at retail for use in performing medical services for compensation are subject to sales tax.

It is noted that the sale of Vitoss to, or its use by, a hospital or other organization qualifying for exemption under Section 1116(a)(4) of the Tax Law would be exempt from the imposition of sales and compensating use tax, even if such entity were using the product in performing medical services for compensation, provided the entity furnished Petitioner with a properly completed exemption certificate within 90 days of the date of sale. See Section 1132(a) of the Tax Law and Section 529.7 of the Sales and Use Tax Regulations.

Cortoss, unlike Vitoss, replaces the hard outer bone structure and acts as a permanent bone filler. Cortoss either completely or partially replaces a missing body part. Assuming that Cortoss is primarily and customarily used for such purpose and is not generally useful in the absence of illness, injury or physical incapacity, Cortoss would meet the prosthetic aid qualifications set forth under Section 528.5 of the Sales and Use Tax Regulations. Cortoss, therefore, qualifies as a prosthetic aid under Section 1115(a)(4) of the Tax Law and its sale to all purchasers is exempt, including purchasers who will use it in performing medical services for compensation.

DATED: June 25, 2002

Jonathan Pessen Tax Regulations Specialist IV **Technical Services Division**

NOTE: The opinions expressed in Advisory Opinions are limited to the facts set forth therein.

|s|