



OKLAHOMA TAX COMMISSION

STATE OF OKLAHOMA

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September 8, 2009

Re: Letter Ruling— Corporation
Our File No. LR-09-001

Dear :

You have requested a letter ruling on behalf of Corporation (" regarding the sales tax implications for sales of its products and biological soft tissue products made from human and animal tissues respectively, in Oklahoma. A Letter Ruling from the Office of General Counsel, Oklahoma Tax Commission, is an "informal written statement of policy or treatment of specific fact situations under Oklahoma law." OKLA. ADMIN CODE 710:1-3-73(e).

This Letter Ruling addresses the following specific **issue**:

Are sales of biological soft tissue products made from human and animal tissues and used as subcutaneous implant for the replacement of soft tissue in reconstructive surgical procedures subject to the State's sales tax pursuant to Okla. Stat. 68 § 1351?

You assert the following **facts** in your request for this Letter Ruling:

is a processor and marketer of biological soft tissue products made from human ("allograft") and animal ("xenograft") tissues. The products include (" e , which is an allograft product used in plastic reconstructive, general surgical, burn and periodontal procedures and c M (" which is a xenograft product used in plastic reconstructive and general surgical procedures. is an acellular dermal matrix derived from donated human skin tissue supplied by USAATB-compliant tissue banks utilizing the standards of the American Association of Tissue Banks (AATB) and Food and Drug Administration's (FDA) requirements. has been classified as banked human tissue by

the FDA. is prepared from human tissue that undergoes a multi-step proprietary process that removes both the epidermis and the cells that can lead to tissue rejection and graft failure. Following transplant, is revascularized and repopulated with the patient's own cells becoming engrafted into the patient.

is predominately used as a subcutaneous implant for the replacement of soft tissue in reconstructive surgical procedures in various areas of the body. is used to repair defects resulting from trauma, previous surgery, hernia repair, infection, tumor resection, mastectomy or general failure of the musculofacial tissue. Specific applications of the product would include use in abdominal wall reconstruction, hernia repair, postmastectomy breast reconstruction, ENT Head & Neck plastic reconstruction, burn graft, wound coverage, mucosal grafts and oral resurfacing.

is porcine dermis (pig skin) that has been processed by to form an acellular tissue matrix. Strattice supports the repair of damaged tissue by allowing rapid revascularization and cell repopulation required for tissue regeneration. Strattice is regulated as a medical device and received 510(k) clearance from the FDA in June 2007 for use as a soft tissue patch to reinforce tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. In October 2007, additional-clearance was received to use Strattice for soft tissue reinforcement in surgical procedures intended to repair rotary cuff tissue.

products are sold to hospitals and medical service providers for use in the repair or replacement of missing or permanently malfunctioning body parts. The products are used in the treatment of individual patients suffering from damaged soft tissues. Although products are incorporated into the patients existing soft tissues, they remain separately identifiable after implantation.

The and Strattice product pricing includes product input costs, manufacturing costs and indirect variable and fixed costs along with a component required for the receipt of a return on the invested capital. is barred under Federal guidelines from owning or passing ownership of human tissue. As a result, in relation to the product offering, is providing a service relating to the processing of the donated human tissue from its original state to the final form suitable for implantation into the recipient patient. The Strattice product is manufactured from porcine or pig based tissue and is therefore owned by prior to sale to the recipient medical service provider. The and Strattice products are prescribed by a physician for the patients on whom they are used.

The following **analysis** relies on the facts you present:

The Oklahoma Sales tax Code (68 O.S. §1350 *et seq.*) imposes “a tax upon the sale of tangible personal property and services *not otherwise exempted*, to the consumer.” 68 O.S.

§1351. (Emphasis added.) A 'sale' is "the transfer of either title or possession of tangible personal property for a valuable consideration regardless of the manner, method, instrumentality, or device by which the transfer is accomplished in this state...." 68 O.S. §1352(15). "Consideration" includes services performed or work done on behalf of the vendor prior to transfer of such tangible personal property. 68 O.S. §1352(12)(a). The processing fees charged in relation to the product thus constitute "consideration" for the transfer of that product. Therefore, the transfer of is subject to Oklahoma sales tax unless otherwise exempted.

The terms of 68 O.S. §1357.6(A) provide:

Effective July 1, 1992, there are hereby exempted from the tax levied by Section 1351 et seq. of this title sales of drugs for the treatment of human beings, medical appliances, medical devices and other medical equipment including but not limited to corrective eyeglasses, contact lenses, hearing aids, **prosthetic devices, as defined in subsection C of this section**, durable medical equipment, as defined in subsection D of this section, and mobility enhancing equipment, as defined in subsection E of this section, **when administered or distributed by a practitioner, as defined in subsection B of this section**, who is authorized by law to administer or distribute such items or when purchased or leased by or on behalf of an individual for use by such individual under a prescription or work order of a practitioner who is authorized by law to prescribe such items and when the cost of such items will be reimbursed under the Medicare or Medicaid Program.
(Emphasis added.)

Physicians are included in the definition of 'practitioner'. 68 O.S. §1357.6(B).

The terms of 68 O.S. §1357.6(C) provide:

The term "prosthetic device" means a replacement, corrective or supportive device, including repair and replacement parts for same, worn on or in the body to:

1. Artificially **replace** a missing portion of the body;
2. Prevent or correct physical deformity or malfunction; or
3. **Support** a **weak** or deformed portion of the body.

Provided, the term shall not include corrective eyeglasses, contact lenses or hearing aids.
(Emphasis added.)

To the extent a tax is not paid on the transfer of title or possession of tangible personal property in this state, the Oklahoma Use Tax Code (68 O.S. §1401 *et seq.*) levies an excise tax on the storage, use or other consumption of the property. 68 O.S. §1402. However, tangible personal property that is specifically exempted under the Oklahoma Sales Tax Code (68 O.S. §1350 *et seq.*) is exempt from the provisions of 68 O.S. §1401 *et seq.* 68 O.S. §1404(4).

In **conclusion**, because, according to your description, is “used as a subcutaneous implant for the replacement of soft tissue in reconstructive surgical procedures in various areas of the body” and is prescribed by a physician, it meets the definition of a ‘prosthetic device’ under 68 O.S. §1357.6(C)(1). Likewise, because, according to your description, Strattice “supports the repair of damaged tissue”, is used “as a soft tissue patch to reinforce tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membrane” and is prescribed by a physician, it meets the definition of a ‘prosthetic device’ under 68 O.S. §1357.6(C)(3). The use of and Strattice qualify for exemption from the provisions of the Oklahoma Use Tax Code (68 §1401 *et seq.*) provided by 68 O.S. §1404(4).

This Letter Ruling generally may be relied upon only by the taxpayer to whom it is issued, provided that all facts have been accurately and completely stated, and there has been no change in applicable law.

Respectfully,

Assistant General Counsel

APPROVED:

General Counsel