SC PRIVATE LETTER RULING #04-5

SUBJECT: Medical Device Implant (Sales and Use Tax) **REFERENCES:** S. C. Code Ann. Section 12-36-2120(28) (Supp. 2003) SC Regulation 117-332 (Supp. 2003) AUTHORITY: S. C. Code Ann. Section 12-4-320 (2000) S. C. Code Ann. Section 1-23-10(4) (Supp. 2003) SC Revenue Procedure #03-1 SCOPE: A Private Letter Ruling is a written statement issued to a specific taxpayer by the Department to apply principles of law to a specific set of facts or a particular tax situation. A Private Letter Ruling is an advisory opinion; it does not have the force and effect of law and is not binding on the person who requested it or the public. It is, however, the Department's opinion limited to the specific facts set forth, and is binding on agency personnel only with respect to the person to whom it was issued and only until superseded or modified by a change in statute, regulation, court decision, or advisory opinion, providing the representations made in the request reflect an accurate statement of the material facts and the transaction was carried out as proposed.

Question:

Is the sale by XYZ, Inc. of a medical device implant, known as the XProduct, to a doctor for implanting in a patient subject to the sales and use tax?

Conclusion:

The sale by XYZ, Inc. of a medical device implant, known as the XProduct, to a doctor for implanting in a patient is subject to the sales and use tax.

Facts:

XYZ, Inc. is a company located in California which sells an FDA approved medical device implant in the United States. This implant is called a XProduct. It is implanted by a doctor (ophthalmologist) into the patient's tear duct. This prevents drainage and keeps more tears in the eye in order to relieve dry eye syndrome. Once implanted, the implant expands to fit the tear duct and is designed to remain there permanently; however, the doctor can remove it if necessary.

Discussion:

Code Section 12-36-2120(28) exempts from the sales and use tax:

(a) medicine and prosthetic devices sold by prescription, prescription medicines used to prevent respiratory syncytial virus, prescription medicines and therapeutic radiopharmaceuticals used in the treatment of cancer, lymphoma, leukemia, or related diseases, including prescription medicines used to relieve the effects of any such treatment, and free samples of prescription medicine distributed by its manufacturer and any use of these free samples;

* * * *

(e) dental prosthetic devices;

While the statute requires that a prosthetic device, other than a dental prosthetic device, be "sold by prescription" in order to be exempt, that question does not need to be addressed here (see note below). The application of the sales and use tax to the device in question is addressed by the definition of the term "prosthetic device" found in SC Regulation 117-332, which reads in part:

To assist in the administration of this exemption, the Department has adopted definitions for the terms "medicine" and "prosthetic devices" as follows:

"Medicine" - a substance or preparation used in treating disease.

"Prosthetic Device" - an artificial device to replace a missing part of the body.

The sale of prescription lenses that replace a missing part of the eye are exempted from the tax, as for example eyeglasses prescribed for a person whose natural lenses have been surgically removed.

Eyeglasses, contact lens, hearing aids and orthopedic appliances, such as braces, wheelchairs and orthopedic custom-made shoes, do not come within the exemption at Code Section 12-36-2120(28). However, sales of hearing aids are exempt pursuant to Code Section 12-36-2120(38).

Therefore, a device that merely replaces a missing function of the body is not exempt. SC Regulation 117-332 defines a prosthetic device as "an artificial device to replace a missing part of the body." In order for the exemption to apply, the device must be replacing a "missing part" of the body.

Based on the above, the sale by XYZ, Inc. of the XProduct to a doctor for implanting in a patient is subject to the sales and use tax since the device does not replace a missing part of the body.

Note: For a detailed discussion of the requirement that a prosthetic device, other than dental prosthetic device, be "sold by prescription" in order to be exempt, see SC Revenue Ruling #03-2.

SOUTH CAROLINA DEPARTMENT OF REVENUE

s/Burnet R. Maybank III Burnet R. Maybank III, Director

May 13, 2004 Columbia, South Carolina