SC PRIVATE LETTER RULING #05-3

SUBJECT:	Medical Device Implant (Sales and Use Tax)
REFERENCES:	S. C. Code Ann. Section 12-36-2120(28) (Supp. 2004) Act 89 of 2005 (Effective July 1, 2005) SC Regulation 117-332 (Supp. 2004)
AUTHORITY:	S. C. Code Ann. Section 12-4-320 (2000) S. C. Code Ann. Section 1-23-10(4) (Supp. 2004) 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set forth, and is binding on agency personnel only with respect to the person to whom it was issued and only until superseded or modified by a change in statute, regulation, court decision, or advisory opinion, providing the representations made in the request reflect an accurate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 MNO, Inc. of a medical device implant, for use in treating a degenerative spine disease, to a doctor or hospital for implanting in a patient subject to the sales and use tax?

Conclusion:

The sale by MNO, Inc. of a medical device implant, for use in treating a degenerative spine disease, to a doctor or hospital for implanting in a patient is subject to the sales and use tax.

Facts:

MNO, Inc. plans to manufacture and sell an implantable medical device that will be used to treat a degenerative spine disease that mostly affects the elderly, causing pain or numbness when walking or standing and ultimately inhibiting mobility. The device is a motion preserving implant that is placed surgically between spinous processes. The device prevents or corrects a physical deformity or malfunction, but it does not replace a missing part of the body. The surgical procedure will typically be performed by a neurologist or orthopedic surgeon in a hospital setting. As such, the purchaser of the device would typically be a hospital that would purchase the implant device to place in its inventory.

Note: At the time of this document, MNO, Inc. was waiting on U.S. Food and Drug Administration ("FDA") approval to sell the device in the United States.

Discussion:

Code Section $12-36-2120(28)^1$ 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 rheumatoid arthritis, cancer, lymphoma, leukemia, or related diseases, including prescription medicines used to relieve the effects of any such treatment, free samples of prescription medicine distributed by its manufacturer and any use of these free samples;

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(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. SC Regulation 117-332, which was approved by the General Assembly in accordance with Article 1 of Chapter 23 of Title 1 of the S.C. Code of Laws, 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.

¹ The exemption for prescription medicines and therapeutic radiopharmaceuticals used in the treatment of rheumatoid arthritis, or prescription medicines used to relieve the effects of any such treatment for rheumatoid arthritis, became effective on July 1, 2005 pursuant to Act 89 of 2005.

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, or that prevents or corrects a malfunction of the body without replacing a missing part 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.

Finally, Code Section 12-36-110(1)(i) defines the terms "retail sale" and "sale at retail" to include "sales of drugs, prosthetic devices, and other supplies to hospitals, infirmaries, sanitariums, nursing homes, and similar institutions, medical doctors, dentists, optometrists, and veterinarians, if furnished to their patients as a part of the service rendered." This statute further states that "[t]hese institutions, companies, and professionals are deemed to be the users or consumers of the property."

Based on the above, the sale by MNO, Inc. of the device described in the facts to a doctor or hospital (for implanting in a patient) is a retail sale and 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

August 1, 2005 Columbia, South Carolina