

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

TSB-A-14(11)S
Sales Tax
July 2, 2014

STATE OF NEW YORK
COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION

PETITION S101214A

The Department of Taxation and Finance received a Petition for Advisory Opinion from [REDACTED]. Petitioner asks whether its [REDACTED] (X) system is exempt from sales and use tax as a prosthetic device. Alternatively, it asks whether steerable guide catheters and clip delivery systems qualify as medical supplies.

We conclude that X system is exempt from sales and use taxes as a prosthetic aid.

Facts

Petitioner manufactures and sells medical devices that enable the repair of the mitral valve in the treatment of patients suffering from the effects of functional and degenerative Mitral Regurgitation (MR). Use of X system permits the repair of the mitral valve without the need of open heart surgery.

The system is a percutaneous device designed to perform an edge-to-edge reconstruction of an insufficient mitral valve while the heart is beating as an alternative to a conventional surgical approach.

The mitral valve is a one-way valve that separates the left atrium (a chamber in the heart which collects blood from the lungs) from the left ventricle (a chamber in the heart which pumps blood to the rest of the body). A defective mitral valve causes mitral regurgitation (MR): blood flowing backwards into the left atrium because the leaflets (or flaps) of the mitral valve do not close properly and leak. The result of leakage in the mitral valve is a decreased blood flow to the body.

Petitioner's X system consists of two major components:

- a steerable guide catheter, and
- a clip delivery system, which includes a clip.

The clip delivery system places a clip on the mitral valve leaflets, which results in permanent leaflet approximation and a double mitral valve orifice. In laymen's terms, the clip enables the valve to close properly, preventing leakage of blood back into the left atrium of the heart. The delivery system includes a control device that a physician operates to manipulate the

steering mechanism on the handles of the catheter and a delivery system to position the clip down to the mitral valve.

The clip itself is a composite of cobalt and chromium covered with a Dacron fabric, which promotes healing. The clip is preassembled to the tip of the clip delivery system via the gripper line, lock line, and actuator connection to the threaded stud.

To access the left atrium of the heart, a standard transpetical crossing technique is performed by the physician operating the device. The steerable guide catheter is then inserted into the femoral vein and delivered into the left atrium via a guide wire. The clip delivery system is then inserted into the catheter and the clip is properly positioned over the mitral valve. Manipulation of the steering mechanism on the handles of the catheter and delivery system positions the clip down to the mitral valve. The clip is actuated (i.e., opened, closed, locked, and deployed) through manipulation of levers on the handle of the delivery system.

When placement is successful, the clip is closed and deployed from the clip delivery system. If placement of one clip does not result in an acceptable reduction of MR, a second clip may be placed to further reduce MR. If a second clip is installed during the same procedure as the first clip is installed, a second X system will be used for installation but the steerable guide catheter used to install the first clip is also used to install the second clip.

The steerable guide catheter is designed to provide a pathway for the clip delivery system only. Its design is integral to the clip system. The catheter has an internal locking mechanism, which allows the operator to maintain precise steering control of the clip delivery system while in the patient. The delivery system cannot be used alone without the catheter. Nor can the delivery system be used with any other company's guiding catheter.

Petitioner's sells X system on a per procedure basis for a single charge.

Analysis

Tax Law section 1115(a)(4) exempts from sales and use tax the receipts for prosthetic aids, artificial devices, and component parts thereof purchased to correct or alleviate physical incapacity in human beings. Sales tax regulation section 528.5(b)(1) provides that:

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 clip that is attached to the mitral valve constitutes a prosthetic aid. X system is an integral product in that it is sold for single price; the components are not sold separately, and

the delivery component can be used only to insert the clip. The entire product qualifies as a prosthetic aid because the delivery component is merely the means to insert the heart valve clip. Accordingly, X system is exempt from sales and use taxes.

DATED: July 2, 2014

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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. The information provided in this document does not cover every situation and is not intended to replace the law or change its meaning.