Date Issued: November 9, 2016

Georgia Letter Ruling: LR SUT-2016-22

Topic: Medical Devices

This letter is in response to your request for guidance on the application of Georgia sales and use tax to certain medical items sold by [Redacted] (Taxpayer").

Facts as Presented by Taxpayer

Taxpayer sells prescription-only, single-patient use pleural and peritoneal catheter kits (used to drain fluid from around lungs or abdomen) and prescription-only, single-patient use pleural and peritoneal drainage kits (used with long term catheters to drain fluid at a medical facility or at a patient's home). Each kit contains all of the components a clinician needs in order to perform the associated procedure. The kits are described in detail below.

Short Term Temporary Catheter System:

These trays are prescription-only and for single-patient, one-time use, and the trays come with their own drainage kits. The relevant medical procedure requires inserting a temporary catheter in the body cavity, draining the fluid from the cavity, and removing the catheter after drainage, while leaving nothing permanent in the body. The process of inserting the catheter only requires a very small incision, which does not require suture to close. This procedure is done all in one step at a medical facility. The kit has all of the components a clinician needs in order to do this procedure.

Each tray has the following five component sections in order to do the complete procedure:

- 1. Preparation components: Prepares patient and procedure area before catheter insertion.
- 2. Placement components: Makes incision in chest or abdominal area for catheter insertion.
- 3. Closing components: A small incision is made that does not need to be closed with suture. Only gauze is used to dry the area where a bandage will be placed after drainage.
- 4. Drainage components: Attach to catheter to drain chest or abdominal fluid into a fluid collection bag or other container. Post drainage, the catheter and drainage components are removed and discarded.
- 5. Dressing components: Bandage and wrap to cover and protect the catheter incision point after the procedure is finished.

Long Term Permanent Catheter System (which uses two kits)

These kits are prescription-only and for single-patient, one-time use. Two kits have to be used together: one kit to place the catheter in the body and one kit to drain it. The relevant medical procedure requires inserting a permanent catheter in the body cavity (Kit One). Because this procedure is permanent, it requires a much larger incision in the chest which has to be closed with suture. Once the permanent catheter is in place, fluid can be drained at that time or in the future (Kit Two). The benefit of this system is that fluid can be drained in a medical facility or in a patient's home. The kits have all of the components a doctor needs in order to do each of these procedures.

Kit One has the following five component sections:

- 1. Preparation components: Prepares patient and procedure area before catheter insertion.
- 2. Placement components: Makes incision in chest or abdomen area for catheter insertion.

Date Issued: November 9, 2016

Georgia Letter Ruling: LR SUT-2016-22

Topic: Medical Devices

Page 2 of 3

- 3. Closing components: Closes incisions with suture after catheter insertion.
- 4. Drainage components: Attach to catheter to drain chest fluid when needed and consists of drainage tubing, which is coiled and adhered to the chest with bandages and capped.
- 5. Dressing components: Bandage and wrap to cover and protect the catheter area after the procedure is finished.

Kit Two contains preparation items and a plastic vacuum bottle with attached drainage line.

Vertebral Augmentation System:

Taxpayer sells kits for vertebroplasty and kyphoplasty (i.e., surgeries to relieve pain from compression fractures of the spine due to osteoporosis, tumors, or cancer). The Vertebral Augmentation System has all the components necessary to insert bone cement (radiopaque PMMA) into the vertebral body of the spine.

The Vertebral Augmentation System procedure tray includes the following:

- 1. Injector handle
- 2. Mixing motor
- 3. Mallet
- 4. Stainless steel forceps, 14"
- 5. Mixing barrel with radiopaque PMMA
- 6. Monomer in ampoule breaker
- 7. Cement delivery tube
- 8. Cement tube (1)
- 9. Cement tube (2)

Issue

What is the proper application of Georgia sales and use tax to Taxpayer's sales of its Short Term Temporary Catheter System, Long Term Permanent Catheter System, and Vertebral Augmentation System procedure kits?

Analysis

Georgia levies and imposes a tax (subject to certain specific exemptions) on the retail purchase, retail sale, storage, use, or consumption of tangible personal property, certain enumerated services, and utilities. The Georgia Code provides an exemption from the tax for the sale or use of a prosthetic device that is sold or used pursuant to a prescription.²

A "prosthetic device" is a replacement, corrective, or supportive device – including repair and replacement parts for the device – worn on or in the body to either artificially replace a missing portion of the body, prevent or correct a physical deformity or malfunction, or support a weak or deformed portion of the body.³

¹ O.C.G.A. §§ 48-8-1, 48-8-2(31)(A), 48-8-30(a).

² O.C.G.A. § 48-8-3(54).

³ Ga. Comp. R. & Regs. r. 560-12-2-.30(2)(h)(1).

Date Issued: November 9, 2016

Georgia Letter Ruling: LR SUT-2016-22

Topic: Medical Devices

Page 3 of 3

If a prosthetic device can be sold or used only pursuant to a prescription under federal or state law, and title and possession will be permanently transferred to the person to whom a prescription for the device is issued, the entity (including hospitals, clinics, and medical practice groups) transferring the device may purchase the item tax exempt without furnishing form ST-5 (Sales and Use Tax Certificate of Exemption). The entity subsequently may transfer the device tax exempt pursuant to O.C.G.A. § 48-8-3(54) to a natural person to whom a prescription for the device is issued.⁴

Here, the catheters, including tubing and collection containers, and the bone cement sold by Taxpayer meet the definition of prosthetic device. They are devices that are in or on the body to either prevent malfunction, replace a missing portion of the body, or support a weak portion of the body.⁵ Further, since the prosthetic devices sold by Taxpayer can be used only pursuant to a prescription and are permanently transferred to the persons to whom prescriptions are issued, such devices are tax exempt.

In addition to prosthetic devices, the kits contain items, such as scalpels and drapes, that are not prosthetic devices and that do not fall under a specific tax exemption. Although these items are tools necessary for the proper use of the prosthetic devices, they are essentially useless and valueless when considered on their own and are useless and valueless after delivery and deployment of the prosthetic device. Such items represent an inconsequential element of the kit as a whole. As such, inclusion of these items in the kits do not cause the kits, in part or in whole, to be subject to tax.⁶

Ruling

Taxpayer's Short Term Temporary Catheter System, Long Term Permanent Catheter System, and Vertebral Augmentation System procedure kits consist of prosthetic devices and tools necessary for the proper use of the prosthetic devices. These prosthetic devices are tax exempt because they are prescription-only and will be permanently transferred to the patient. The additional tools included in each kit are inconsequential since they are useless and valueless after the delivery and deployment of each prosthetic devices. Consequently, sales of the listed kits are exempt from sales and use tax.

The opinions expressed in this ruling are based upon the information contained in your request and limited to the specific transactions, facts, circumstances, and taxpayer in question. Should the circumstances regarding the transactions change or differ materially from those represented, this ruling may become invalid. Subsequent statutory or administrative rule changes or judicial interpretations of the statutes or rules upon which this ruling is based may subject similar future transactions to different tax treatment than that expressed in this ruling.

⁴ Ga. Comp. R. & Regs. r. 560-12-2-.30(5)(a).

⁵ See Ga. Comp. R. & Regs. r. 560-12-2-.30(2)(h)(3) (providing similar examples of prosthetic devices, including bone cement, urinary collection systems, and colostomy appliances along with necessary equipment for attachment). ⁶ Although not directly on point, the Georgia General Assembly has implied that sales tax does not apply to inconsequential or de minimis elements of a nontaxable transaction even though such elements would be taxable if sold separately. See O.C.G.A. § 48-8-2(3)(D)(iii) ("A transaction that otherwise meets the definition of bundled transaction as provided under this paragraph shall not be a bundled transaction if such transaction is . . . [a] transaction that includes taxable products and nontaxable products and the purchase price or sales price of the taxable products is de minimis. As used in this subparagraph, the term 'de minimis' means the seller's purchase price or sales price of the taxable products.").