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Georgia Letter Ruling No. 2013-01-29-01 Medical & Drugs

This letter is in response to your requests for guidance on the application of Georgia sales and use tax to sales of certain items to hospitals and surgery centers.

**Facts**

Taxpayer is a licensed distributor of a prosthetic device used for bone void filling and fracture repair. The product material is a composition of carbonated apatite and bovine type I collagen. Carbonated apatite is a form of calcium phosphate that closely resembles the mineral phase of natural human bone. The granules are interspersed within the collagen, providing an enhanced osteoconductive scaffold to support bone remodeling. The scaffold is highly porous with ample surface area for absorption of bone marrow aspirate and stem cell attachment. The product is available in pads, strips, blocks, plugs and paste. Upon saturation, bone marrow aspirate may be manipulated as desired. This flexible structure allows the grafts to be shaped based on patient anatomy and surgical environment. Pads, strips, blocks and plugs may be compressed, folded, trimmed or layered, while hydrated paste may be molded. Taxpayer sells this product to hospitals and surgery centers in Georgia to be surgically implanted in patients.

Taxpayer provided documents from the United States Food and Drug Administration (“FDA”) indicating that the product is a Class II device, which means it can only be sold to patients pursuant to a medical prescription of a licensed medical professional.<sup>1</sup>

Taxpayer is also a licensed distributor of a combination drug device product that is pending marketing approval by the FDA as a Class III medical device. This product was developed as a fully synthetic replacement to autograft in hindfoot and ankle surgery. It consists of two components: recombinant human platelet-derived growth factor and beta-tricalcium phosphate. The product is supplied as a kit for a single use only. At the point of use, the two primary components are combined in entirety, mixed and subsequently applied to the surgical site. The beta-tricalcium phosphate component of the product is a highly porous, resorbable and osteoconductive scaffold which provides a framework for bone regeneration, aids in preventing

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<sup>1</sup> 21 C.F.R. § 801.109.

soft tissue infiltration, and promotes stabilization of the blood clot. The recombinant human platelet-derived growth factor, also known as becalplermin, acts by stimulating the recruitment and proliferation of a variety of cell types. The product is placed on defects, such as gaps between bones where a surgeon is trying to achieve fusion. It provides scaffolding for natural occurring tissue (bone) regeneration and is gradually resorbed by the body and turned into bone. The presence of the protein stimulates this naturally occurring biological process.

### **Issues**

Are Taxpayer's sales of these products to hospitals and surgery centers in Georgia subject to sales and use tax?

### **Analysis**

All retail purchases and sales of tangible personal property are taxable unless provided for otherwise.<sup>2</sup> Tax is levied and imposed upon the retail purchase, retail sale, rental, storage, use, or consumption of tangible personal property and on certain services that occur in this state.<sup>3</sup> "Retail sale" or a "sale at retail" means a sale to a consumer or to any person for any purpose other than for resale of tangible personal property or certain services.<sup>4</sup>

The tax applies to all retail sales of drugs, medicine, medical supplies and equipment unless specifically exempt.<sup>5</sup> Code Section 48-8-3(54) provides an exemption from sales and use tax for "[t]he sale or use of any durable medical equipment that is sold or used pursuant to a prescription or prosthetic device that is sold or used pursuant to a prescription". In addition, Code Section 48-8-3(47) provides an exemption for "[t]he sale or use of drugs which are lawfully dispensable only by prescription for the treatment of natural persons . . ."

To qualify as an exempt prosthetic device, the particular item must initially meet the definition. Specifically, "prosthetic device" means a replacement, corrective, or supportive device...worn on or in the body to artificially replace a missing portion of the body; or prevent or correct physical deformity or malfunction; or support a weak or deformed portion of the body.<sup>6</sup> If an item meeting this definition can, under federal or state law, be sold or used only pursuant to a prescription, and title and possession of the item will be permanently transferred from a hospital or surgery center to a natural person to whom a prescription for the item is issued, the hospital or surgery center may purchase the item tax exempt without furnishing form ST-5 (Sales and Use Tax Certificate of Exemption).<sup>7</sup> The hospital or surgery center may then 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.

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<sup>2</sup> O.C.G.A. §§ 48-8-1 and 48-8-30(b).

<sup>3</sup> O.C.G.A. § 48-8-30.

<sup>4</sup> O.C.G.A. § 48-8-2(31).

<sup>5</sup> Ga. Comp. R. & Regs. r. 560-12-2-.30, effective November 19, 2012.

<sup>6</sup> O.C.G.A. § 48-8-2(29).

<sup>7</sup> Ga. Comp. R. & Regs. r. 560-12-2-.30(5)(a).

## **Rulings**

The first product meets the definition of “prosthetic device”. Under federal law, it can only be sold or used pursuant to a medical prescription. Title and possession of the product are permanently transferred to a natural person to whom it is prescribed. Therefore, Taxpayer’s sales of this product to hospitals and surgical centers are exempt from Georgia sales and use tax.

The second product also meets the definition of “prosthetic device”. It is the Department’s understanding that Taxpayer is currently seeking FDA approval of this product as a Class III medical device. If the FDA approves the product as a Class III medical device and restricts it to “prescription use” only, Taxpayer’s sales of the product to hospitals and surgical centers will also be exempt from Georgia 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 and taxpayer in question. Should the circumstances regarding the transactions change, or differ materially from those represented, then this ruling may become invalid. In addition, please be advised that subsequent statutory or administrative rule changes or judicial interpretations of the Statutes or Rules upon which this advice is based may subject similar future transactions to a different tax treatment than that expressed in this response.