North Carolina Department of Revenue

Pat McCrory
Governor

Lyons Gray
Secretary

March 12, 2013

[redacted]

Attention: [redacted]

Re: [redacted]
FEIN: [redacted]

Dear Mr. [redacted]

We have your letter dated May 22, 2012, in which you request a ruling from the Department regarding your above-referenced client's North Carolina sales and use tax liability on its sales of a particular product. We apologize for the delay in our response.

You advise that your client, [redacted]. ("[redacted]"), is a biotechnology company specializing in the development and commercialization of "drug-device combination products to promote the healing of [redacted] injuries and diseases. . . ." Your client plans to sell a new product, [redacted] ("[redacted]"), to hospitals and surgery centers in this State for use in surgery. The product, [redacted], "is a [redacted] material intended for use in combination with autologous bone marrow for bone void filling and fracture repair of the pelvis and extremities. The product material is a composition of [redacted] is a form of calcium phosphate that closely resembles the mineral phase of natural human bone. The granules are interspersed within the [redacted] providing an enhanced osteoconductive scaffold to support bone remodeling. The scaffold is highly porous with ample surface area for absorption of [redacted] and stem cell attachment. . . . Upon saturation with [redacted] 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. Hydrated paste may be molded." [redacted] has been approved by the FDA as a Class II medical device for prescription use only.

Tangible personal property, certain digital property, and certain services your client sells at retail to customers or purchases for storage, use, or consumption in this State are subject to sales or use tax, unless specifically exempt by statute. N.C. Gen. Stat. § 105-164.13(12)a. provides an exemption from sales and use tax for sales of prosthetic devices for human use. N.C. Gen. Stat. § 105-164.3(30b) defines the term "prosthetic device" as "[a] replacement, corrective, or supporting device worn on or in the body that meets one of the conditions of this subdivision. The term includes repair and replacement parts for the device.

a. Artificially replaces a missing portion of the body.
b. Prevents or corrects a physical deformity or malfunction.
c. Supports a weak or deformed portion of the body."

Based on the information provided, it is our opinion that your client's sales of [redacted] are sales of prosthetic devices within the meaning of N.C. Gen. Stat. § 105-164.3(30b) provided such are for human use and are, therefore, exempt from sales tax under the provision of N.C. Gen. Stat. § 105-164.13(12)a.

This ruling is based solely on the facts submitted to the Department of Revenue for consideration of the transactions described. If the facts and circumstances given are not accurate, or if they change, then the taxpayer requesting this ruling may not rely on it. If a taxpayer relies on this ruling and the Department discovers, upon examination, that the fact situation of the taxpayer is different in any material aspect from the facts and circumstances given in this ruling, then the ruling will not afford the taxpayer any protection. It should be noted that this document is not to be cited as precedent and that a change in statute, a regulation, or case law could void this ruling.

If you have any questions, you may reach me at the number listed below.

Very truly yours,

[redacted]
Administration Officer
Sales and Use Tax Division

[redacted]

cc: [redacted], Director of Sales and Use Tax Division