



North Carolina Department of Revenue

Beverly Eaves Perdue  
Governor

David W. Hoyle  
Secretary

April 12, 2012

[Redacted]

Attention: [Redacted], CPA

Re: [Redacted]  
FEIN: [Redacted]

Dear Mr. [Redacted]

We have your letter dated December 15, 2011, 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.

You advise that your client, [Redacted], [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. "The product, [Redacted], is a combination product pending approval by the [Redacted] as a Class [Redacted]." [Redacted] was developed as a [Redacted].

[Redacted] consists of two components: [Redacted]. It 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." [Redacted]

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 provisions 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