

M e m o r a n d u m**425.0148**

To: Out-of-State - - Auditing

Date: October 27, 1983

From: Charles J. Graziano

Subject: C--- Corp.

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Your memo of September 19, 1983 to Out-of-State Audit had been referred to me for reply. Your inquiry concerns the application of tax to the sale of articles which are implanted in the human body.

We understand that C--- Corporation is currently being audited for the period of 1/1/80 to 3/31/83. C--- sells medical devices, such as pacing and neurosurgical systems, which are implanted in the human body. At issue during a prior audit of this taxpayer was whether or not articles sold by the taxpayer were for permanent implantation in the human body as required by Section 6369(c)(2) and Sales and Use Tax Regulation 1591(b)(2). You state that after reviewing several recent opinions issued by the legal staff regarding prosthetic devices, the auditor is left with the impression that anything implanted in the body (permanent or not) is exempt from tax as assisting in the functioning of a natural part of the human body. In support of this conclusion, you cite Ms. Armstrong's letter of 3/10/83 concerning the sale of balloon catheters which provide assistance to a failing heart by increasing the diastolic pressure and coronary artery flow. These balloon catheters are not permanently implanted in the human body. As was stated in Ms. Armstrong's letter, we are of the opinion that this type of balloon catheter qualifies as an exempt prosthetic device under Section 6369(c)(4) of the Revenue and Taxation Code and Regulation 1591(b)(5).

Your questions and our response are as follows:

1. "Should anything implanted in the body be considered a prosthetic device?"

No. In order to qualify as a prosthetic device under Regulation 1591(b)(5), a device must be fully worn on or in the body of the user and either (1) replace a natural part of the body, or (2) assist in the functioning of a natural part of the human body. Specifically excluded from the term "prosthetic device" are dentures, auditory, ophthalmic, and ocular devices and appliances. Therefore, an implanted device which is specifically excluded under Regulation 151(b)(5), such as an auditory device, does not qualify as an exempt prosthetic device. Such an implanted device, however, could qualify as a medicine under Regulation 1591(b)(2) if it does not replace any part of any natural organ and is permanently implanted. (See our response to your question #4 below.)

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2. "Is there a difference between 'implanted in the body' and 'worn in the person'?"

The term "worn in the person" is broader in scope than the term "implanted." The term "implanted" is generally accepted to mean the insertion or the grafting into the intact tissues of the recipient, and usually requires some sort of surgical operative procedure. Devices which are "worn in" the body of the user are not necessarily implanted. For example, dentures and hearing aids are not usually "implanted;" however, such devices are considered to be "worn in" the body of the user.

3. "Is there a difference between 'natural organ' and 'natural part of the body'?"

A "natural organ" is generally defined to be a differentiated structure performing some specific physiological function, such as a heart, an eye, or a kidney. The term "natural part" is much broader in scope and includes any part of the body, whether or not such part constitutes a differentiated organ. For example, an artery is not considered to be a "natural organ," whereas it constitutes a "natural part" of the body.

4. "Does Reg. 1591(B)(5) override 1591(B)(2) requirement of "permanently implanted?"

No. Sections (b)(2) and (b)(5) of Regulation 1591 provide separate and distinct definitions of the term "medicine," and apply independently to the sale of the medical devices. Although Sections (b)(2) and (b)(5) somewhat overlap in their scope, effective October 1, 1977, a medical device may separately qualify as a "medicine" under one or both of these sections. As described in Ms. Armstrong's letter, a device which is "temporarily" implanted in the body does not qualify as an exempt medicine under Regulation 1591(b)(2). The same temporary device, however, can qualify as an exempt "medicine" under Regulation 1591(b)(5), since this particular section does not require the device to be permanently implanted.

CJG:ba

cc: Mr. D. J. Hennessy