

**STATE BOARD OF EQUALIZATION**

(916) 324-3828

February 15, 1991

Mr. D--- B---
Tax Accountant, S--- Inc.
XXXX --- Drive
--- ---, Minnesota XXXXX-XXXX

RE: SC OH XX-XXXXXX

Dear Mr. B---:

I am writing this in response to your letter of December 18, 1990, and to our telephone conversation of February 1, 1991. You have requested an opinion as to whether or not your company's sales of the Angioplasty Catheter and the Membrane Oxygenator are subject to California sales or use tax.

OPINIONA. Sales and Use Tax Generally

In California, except where specifically exempted by statute, Revenue and Taxation Code Section 6051 imposes an excise tax, computed as a percentage of gross receipts, upon all retailers for the privilege of selling tangible personal property at retail in this state. (Unless otherwise stated, all statutory references are to the Revenue and Taxation Code.) "[I]t shall be presumed that all gross receipts are subject to tax until the contrary is established. The burden of proving that a sale of tangible personal property is not a sale at retail is upon the person who makes the sale ..." (§ 6091.) Likewise, Section 6201 imposes a use tax on the storage, use, or other consumption in this state of tangible personal property purchased from any retailer for storage, use, or other consumption in this state unless otherwise exempted from taxation by statute.

B. Prescription Medicines

Section 6369(a) interpreted and implemented by Title 18, California Code of Regulations, Regulation 1591 (Regulations are Board rulings that have the force and effect of law), provides that sales of medicines, when prescribed and sold or furnished under certain conditions, are exempt from sales or use tax. The statute goes on to specifically exclude from the definition of "medicines" items in the nature of instruments, apparatus, appliances, contrivances, devices, or other equipment

or article and the replacement parts thereof (Reg. 1591(c)(2).) As a general rule, then, items used to apply medicine or treatment to the patient are not considered to be medicines. Over the years, however, the Legislature has provided exceptions to that general rule.

C. Catheters and Prosthetics

Prior to October 1, 1977 only those catheters which were “implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remained permanently or dissolved in the body” were considered exempt medicines. (§6369(c)(2); Regulation 1591(b)(2).

Effective October 1, 1977, Revenue and Taxation Code section 6369 was amended to add:

“Mammary prostheses, and any appliances and related supplies necessary as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste.” (Section 6369(g).)

“Prosthetic devices, and replacement parts for such devices, designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body.” (Section 6369(c)(4).)”

As a result of the 1977 amendments, certain drainage catheters were considered exempt medicines under section 6369(g) because they were utilized as a result of a surgical procedure by which “an artificial opening is created in the human body for the elimination of natural waste.” Certain other drainage catheters were still considered taxable because they were utilized through a “natural opening.” Since 1977 several types of drainage catheters have been classified as exempt medicines even though they were utilized through a natural opening. The main requirement was that the catheters had to be worn on the person of the user or be permanently implanted. The interpretation to allow drainage catheters used as a result of a natural opening was an extension of the exemption provided to catheters in section 6369(g). As a consequence, the requirement for post-surgical use was maintained. Certain other catheters which are used for diagnostic purposes, irrigation, feeding and administration were not considered exempt under any part of section 6369 and tax applies to their sale.

In summary, catheters are generally taxable, with three major exceptions: (1) catheters which are permanently implanted are exempted under section 6369(c)(2); (2) catheters which are used for drainage purposes through artificial openings are non-taxable under section 6369(g) dealing with ostomy materials (this exemption includes supplies); and (3) catheters or other types of drainage devices used for drainage through natural openings are non-taxable as prosthetic devices under section 6369(c)(4). Catheters may also be exempted if an integral and necessary part of another exempt item.

Prosthetics is the art or science of replacing or assisting, by artificial means, body parts that are missing or defective. (Dorland's Illustrated Medical Dictionary, 24th ed., p. 1230) In our view, while sub-section (c)(4) does not require permanent implantation, it is not intended to include devices used merely to temporarily replace or assist otherwise functional body parts during a surgical procedure or operation for either treatment or testing.

D. Tax Consequences to S---, Inc.

1. Angioplasty Catheter.

In your letter, you describe the use of this item as follows:

“The coronary angioplasty catheter is a balloon-tipped catheter used in the treatment of coronary artery disease.

“The product is used during a surgical procedure performed in a hospital under local anesthesia by a cardiologist. The procedure involves inserting a balloon-tipped catheter into a major artery through an incision in the leg or arm and guiding it through the coronary arteries to the site of blockage or occlusion. The deflated balloon is positioned across the occluded area and inflated and deflated several times, resulting in expansion of the arterial opening to improve blood flow. The product is discarded after each procedure.”

From the facts you give, this catheter is apparently used solely for surgical treatment. It is not permanently implanted, used for drainage as a result of surgery, nor to assist a natural part of the human body to function properly. It does not fit clearly within one of the above exemption. As a result, we conclude that the Angioplasty Catheter is an appliance, etc., excluded from the definition of “prescription medicine” by Regulation 1591(c)(2). Sales of this appliance are thus subject to tax.

2. Membrane Oxygenator

In your letter, you describe the operation of this item as follows:

“Membrane Oxygenators add oxygen to and remove carbon dioxide from a patient's blood during surgery.

“The oxygenator is used primarily during open-heart surgery procedures, and substitutes for the patient's lungs during the operations. The unit cannot be reused and is discarded after each procedure.”

During our telephone conversation, you clarified the oxygenator's use. It now appears that the oxygenator is used solely during surgery. I assume that it consists of tubing connected to the patient and through which the blood flows and further that it is connected to a device which moves the blood through the tubing.

As noted above, while there is no requirement for a prosthesis to be permanently implanted, it must be used for more than just to temporarily assist an organ during surgical procedures. Additionally, for a device to be considered a drainage device, it must operate on its own. If connected to another device, we consider that it is related to that device and qualifies for the exemption only if the device does. Since the oxygenator is part of a larger system used only during surgery, we conclude that it is not a "medicine" under Regulation 1591(c)(2). Its sales are subject to tax.

Enclosed for your information is a copy of Regulation 1591. I hope the above discussion has answered your question. If you need anything further, please do not hesitate to write again.

Sincerely

John L. Waid
Tax Counsel

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