STATE OF CALIFORNIA

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September 16, 1996

Mr. M--- K---C--- & L--- ------ Park Building, Suite XXXX XXX Xrd Avenue South ---, -- XXXXX

Re: [No Permit Number] Heart/Lung Surgery Devices

Dear Mr. K----:

I am responding to your letter dated August 15, 1996, to the Legal Division. You indicate your understanding that your client's sales are not subject to tax under Regulation 1591 and ask for verification of your understanding.

You describe your client's operation as follows:

"Our client is engaged in the design, development, manufacture and marketing of specialty medical devices for heart/lung bypass surgery and long-term respiratory support. The devices are single-use, disposable products. The products are sold to doctors, clinics and hospitals located in various states including California. We seek advice of the sales and use tax implications on the following products related to the above fields:

- "1. Blood oxygenators and related blood reservoirs. This equipment is used to add oxygen and store the blood while the blood is outside the body during heart bypass surgery.
- "2. Cardioplegia delivery system. This system is used to infuse specially formulated solutions, which often include oxygenated blood, directly into the patient's coronary arteries while the heart is stopped during bypass surgery. In addition to delivering nutrients to the heart, these solutions are used to arrest the heart and maintain prescribed temperatures.

"3. Custom tubing packs. These packs contain all the devices used in a heart/lung bypass procedures. The exact contents of each pack are determined by each customer."

OPINION

A. 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.) 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 use, storage, or other consumption in this state, unless otherwise exempted from taxation by statute, purchased for use in this state in a transaction not subject to sales tax.

Please note that the sales tax is imposed upon the retailer for the privilege of selling tangible personal property in this state while the use tax is upon the purchaser who uses, stores, or otherwise consumes such property here. Pursuant to agreement, the purchaser may reimburse the retailer for its sales taxes paid (Civ. Code 1656.1), but the retailer must collect the use tax from the purchaser if engaged in business in this state. (§ 6303.)

B. Prescription Medicines.

Section 6369, interpreted and implemented by Title 28, California Code of Regulations, Regulation 1591, provides that sales of medicine, when prescribed and sold or furnished under certain conditions for the treatment of a human being, are exempt from sales or use tax. (Reg. 1591(a).) Subdivision(b)(1) defines "medicine" to "mean and include any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and which is commonly recognized as a substance or preparation intended for such use." However, Regulation 1591(c)(2) adds that "medicines" do not include "articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof." (Sales and Use Tax Regulations are Board promulgations which have the force and effect of law.) As a rule, then, items used to diagnose a condition or to apply medicine or treatment to the patient are not considered to be medicines.

C. Tax Consequences.

We have previously concluded that blood oxygenators are devices whose purpose is to substitute for the patient's lungs during open-heart surgery. (Annot. 425.0518 (2/15/91). Sales and Use Tax Annotations are excerpts from previous Board Staff opinion letters and serve as guides to Staff positions.) The blood reservoirs are used to store the blood while it is outside the body during surgery. Infusion systems are also such devices, with one limited exception. (See, Reg. 1591(B)(7).) The custom tubing pack, related as it is to a taxable device, are themselves devices. We thus conclude that the blood oxygenators and reservoirs, the cardioplegia delivery system, and the custom tubing packs are devices, instruments, or appliances excluded from the definition of "medicines" under Regulation 1591(c)(2) with the result that their sales are subject to tax.

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 Senior Tax Counsel

JLW:cl

cc: Out-of-State District Administrator