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June 5, 1996

E. L. SORENSEN, JR.
 Executive Director

Ms. F--- A--- S---
 Director of Operations
 H---, Inc.
 XXXX --- Lane
 ---, CA XXXXX

SR -- XX-XXXXXX
 Nasal Splints
 Origin Tacker System

Dear Ms. S---:

I am answering your two letters dated April 4, 1996 to the Legal Division. You ask for advice regarding the application of sales tax to H---'s sales of various Nasal Splints and of the Origin Tacker Endoscopic Stapler System. You describe the operation of these items in your letters and attached copies of flyers which also describe them.

OPINION

A. Sales and Use Tax Generally.

In California, except where specifically exempted by statute, Revenue and Taxation Code Section 6051 imposes a sales 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.) “Exemptions from taxation must be found in the statute.” (Market St. Ry. Co. v. Cal. St. Bd. of Equal. (1953) 137 Cal.App.2d 87, 96 [290 P.2d 201.]) “The taxpayer has the burden of showing that he clearly comes within the exemption.” (Standard Oil Co. v. St. Bd. of Equalization (1974) 39 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

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.

Regulation 1591(b) does provide that certain items which might otherwise be considered as being devices, etc., are defined as “medicines.” Regulation 1591(b)(2) includes sutures, whether or not permanently implanted.

C. Tax Consequences.

1. Nasal Splints.

There are five of these items on which you inquire. You indicate that the Soft-Form External Thermo Plastic Splint and the Soft-Form External Aluminum Nasal Splint are external splint/dressings used following surgery and removed 7-10 days after surgery. They are not implanted. According to the flyers, the Bivalve and Custom-Cut Splints are put in the nose temporarily after rhinoplasties to keep the air passages open. They are also removed after 7-10 days and are not permanent

These facts indicate that the Nasal Splints immobilize the nose area to permit healing and do not otherwise support the body structure. Splints are one of the items listed in Regulation 1591(c)(2) as being devices, appliances, etc. excluded from the definition of “medicine.” Therefore, sales of these items are subject to tax.

2. Origin Tacker System.

You describe the system as follows:

“The Origin Tacker System ... is an endoscopic stapling system designed to permit stapling or fixation of tissue and prosthetic mesh during surgical procedures. This device works in basically the same fashion as other manufacturers endoscopic devices but the design of the tacks is different from the standard staple.

“The system consists of a limited reuse handle and disposable delivery tubes which hold the tacks used in the fixation of the tissue and or prosthetic mesh. The tacks are implanted into the body as a permanent implant in much the same way as the surgical staple or suture material would be.”

You attached to your letter a flyer describing the system and a copy of a portion of an article apparently from the November 1995 issue of Surgical Rounds on the use of the tacker system for affixing and stabilizing prosthetic mesh in laparoscopic hernia repair. The article describes the operation of the device as follows:

“The spiral tacking device (Origin Tacker) delivers helical titanium coils. . . . Twenty spiral tacks are loaded into a 5-mm-diameter tubular delivery system. Upon depression of the handles, the spiral tack is advanced in a corkscrew fashion through the mesh and into tissue. Release of the handle advances the next coil into position for delivery.

“The spiral tacking device employs a disposable delivery tube and a handle that may be sterilized for limited reuse.”

The flyer states as an advantage of the product that the design “enables atraumatic tack removal.”

We have previously determined that skin staples qualify as sutures under Regulation 1591(b)(2). (Annot. 425.0853 (6/11/91).) The tacks themselves appear to be a technological advance over staples, operate in much the same way, and perform the same use -- a piece of wire uniting two pieces of skin. As a result, we conclude that sales of the tacks are exempt from tax under this authority. The article indicates, however, that the tubular delivery system is not shipped pre-loaded. Also, the handle is reusable. We conclude that the delivery system and the handle are instruments excluded from the definition of “medicines” under Regulation 1591(c)(2) with the result that their sales are subject to tax. The flyer indicates that comes in a kit. Consequently, the entire sales price of the kit is subject to tax unless the price of

the kit is separated between taxable and non-taxable items, in which case tax applies only to the price of the taxable items.

For your information, I have included 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
Senior Tax Counsel

JLW:sr

Enclosure: Reg. 1591

cc: Sacramento District Administrator - KH