

M e m o r a n d u m**425.0907**

To: David H. Levine

Date: October 4, 1996

From: John L. Waid

Subject: Annotation Section 425.0000(b)
Specific Items Classified

Attached hereto please find a copy of my recent letter to X-----, regarding female urinary incontinence products. They likened these items to TENS devices. It is not our policy to expand the TENS exemption beyond the specific facts of the TENS device itself. The item at issue did qualify as a straight-ahead prosthetic device. As a result, I suggest annotation of this letter to emphasize the distinction between the two. I suggest the following language:

"Urinary Incontinence Products (Female). The Innova female urinary incontinence product causes involuntary contractions of the pelvic musculature and urinary sphincter in order to treat or cure incontinence. This device is composed of an externally worn, microprocessor-based electrical neuromuscular stimulator that activates a tampon-like vaginal electrode worn internally. We conclude from this description that while these devices are not akin to TENS units they do qualify as prosthetic devices if they are fully worn on the body of the user. Typically, a TENS unit is designed to relieve pain through the use of electrical impulses which are emitted from the unit directly to the area of the body in which the patient is experiencing pain. By contrast, the female urinary incontinence device appears to assist the vaginal sphincter in performing its natural function--staying closed in order to retain urine, and opening to evacuate the bladder under the control of the patient. This use fits precisely the regulatory definition. The Liberty Female Urinary Incontinence Product, if fully worn on the body of the user, is thus a prosthetic device within the meaning of Regulation 1591(b) (5) with the result that furnishing such products to patients pursuant to the written order of a licensed physician is not subject to tax. (Reg. 1591 (i) .)"

JLW:cl



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LEGAL DIVISION – MIC: 85
450 N STREET, SACRAMENTO, CALIFORNIA
PO BOX 942879, SACRAMENTO, CALIFORNIA 94279-0082
TELEPHONE (916) 324-2655
FAX (916) 323-3387

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October 4, 1996

[No Permit Number]
Liberty Feminine Urinary
Incontinence Product

Dear X-----,

I am responding to your letter dated August 2, 1996, to Executive Director E. L. Sorensen, Jr. You ask for advice that Utah Medical's sales of the Liberty Feminine Urinary Incontinence Product are not subject to tax. You attached to your letter a partial copy of a letter on Board letterhead from which the date and taxpayer information have been excised; the signature page is also missing. The author of that letter likened the device at issue therein, the Innova Female Urinary Incontinence Product, to a Transcutaneous Electrical Nerve Stimulator (TENS) and cited Annotations 425.0885 (11/15/77 & 4/11/83) and 425.0247.5 (3/14/90) for authority that such devices are considered prosthetic devices the sales of which are exempt from tax when the device is furnished pursuant to the written order of a licensed physician.

You state that Utah Medical's product is equivalent to the Innova product. The letter attached to your letter terms the Innova "an electro-therapeutic device used by a patient for in-home treatment of incontinence" and describes its operation as follows:

"The Innova causes involuntary contractions of the pelvic musculature and urinary sphincter in order to treat or cure incontinence. This device is composed of an externally worn, microprocessor-based electrical neuromuscular stimulator that activates a tampon-like vaginal electrode worn internally."

We presume from your statement that the Liberty product works the same way and has the same components as does the Innova device. We also assume that the "tampon-like vaginal electrode" is not implanted and may be removed at any time. The device seems to be fully worn on the body of the user.

OPINION:

Regulation 1591 provides, in part, as follows:

"(b) The term "medicines" means and includes:

* * *

(5) Prosthetic devices, or their replacement parts, 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, other than auditory, ophthalmic and ocular devices or appliances, and other than dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth and other dental prosthetic materials and devices."

From the description you provide, we are of the opinion that these devices are not akin to TENS units for the purposes of this analysis. However, we conclude that they do qualify as prosthetic devices. Typically, a TENS unit is designed to relieve pain through the use of electrical impulses which are emitted from the unit directly to the area of the body in which the patient is experiencing pain. By contrast, the female urinary incontinence device appears to assist the vaginal sphincter in performing its natural function – staying closed in order to retain urine, and opening to void the bladder under the control of the patient. This use fits precisely the regulatory definition. The Liberty Female Urinary Incontinence Product is thus a prosthetic device within the meaning of Regulation 1591 (b) (5) 'with the result that furnishing such products to patients pursuant to the written order of a licensed physician is not subject to tax. (Reg. 1591 (i) .)

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

Cc: Ms. Rosie Ornelas-Odarte (MIC:40)