OFFICE OF TAX APPEALS

STATE OF CALIFORNIA

In the Matter of the Appeal of:	) OTA Case No. 19085143
	) CDTFA Account No. 102-305747
MEDIFOCUS, INC.	) CDTFA Case ID 1002680
	)
	)
	)

OPINION

Representing the Parties:

For Appellant: Dr. W. Jow, Chief Executive Officer
Dr. S. Katz, Medical Director

For Respondent: Amanda Jacobs, Tax Counsel III

S. BROWN, Administrative Law Judge: Pursuant to Revenue and Taxation Code (R&TC) section 6901, Medifocus, Inc. (appellant) appeals a decision issued by respondent California Department of Tax and Fee Administration (CDTFA)[1] denying appellant's claim for refund of $34,435.94 in connection with an audit for the period August 1, 2012, through June 30, 2015.[2]

Appellant waived its right to an oral hearing and, therefore, the matter is being decided based on the written record.

[1] Sales and use taxes were formerly administered by the State Board of Equalization (BOE). In 2017, functions of BOE relevant to this case were transferred to CDTFA. (Gov. Code, § 15570.22.) For ease of reference, when this opinion refers to acts or events that occurred before July 1, 2017, "CDTFA" shall refer to BOE; and when this opinion refers to acts or events that occurred on or after July 1, 2017, "CDTFA" shall refer to CDTFA.

[2] In its August 12, 2019 Request for Appeal filed with the Office of Tax Appeals (OTA), appellant stated the dollar amount of the appeal as $53,561.27 and identified two liability periods at issue: August 2012 through June 2015; and June 2016 through April 2019. However, the Notice of Determination (NOD) at issue in the present case is dated July 22, 2016, and pertains only to the liability period August 1, 2012, through June 30, 2015. Moreover, the liability amount in the July 22, 2016 NOD was only for use tax of $27,051.94, plus applicable interest; according to CDTFA's Decision, appellant has paid that liability via a series of payments totaling $34,435.94. Thus, the present appeal pertains only the liability stemming from the July 22, 2016 NOD, and does not address any liability period outside the period August 1, 2012, through June 30, 2015.

ISSUE

Whether a refund is warranted for use tax paid on appellant's withdrawal of tangible personal property (TPP) from its resale inventory.[3,4]

FACTUAL FINDINGS

1. Appellant is a Canadian corporation with headquarters in Maryland.[5]
2. Appellant was a retailer of the Prolieve Thermodilatation System (Prolieve System), which is designed to treat symptoms of benign prostatic hyperplasia (i.e., enlarged prostate) in men.
3. According to CDTFA's audit working papers, appellant purchased the Prolieve Systems from Lake Region Medical. All of the transactions picked up during the audit were shipped to addresses in California.
4. The Prolieve System uses microwave thermotherapy and balloon compression technology to heat and dilate the prostate for the purpose of reducing the size of enlarged prostate tissue. Components of the Prolieve System include a catheter, a sterile water bag, and a heat exchange cartridge. Use of the Prolieve System occurs during a 45-minute outpatient procedure in which a physician inserts the catheter into the patient's urethra. An antenna inside the catheter transmits heat to the prostate, and a small balloon that is part of the catheter inflates within the urethra. The catheter is a single-use device that does not remain permanently implanted in the patient, and typically is removed from the patient immediately following the procedure.

[3] According to CDTFA's Decision, appellant has made a series of payments totaling $34,435.94, for which appellant has filed a timely claim for refund under R&TC section 6902.6. If a refund of use tax is warranted, a refund of applicable interest would likewise be warranted. (R&TC, § 6396; Cal. Code Regs., tit.18, § 1703(b)(1)(C).)

[4] The evidence and argument for this appeal do not indicate in what manner appellant withdrew the Prolieve Systems from resale inventory (e.g., to give its products to California hospitals as promotional items without charge). This, and how CDTFA calculated the taxable measure on such withdrawals, are not at issue or in dispute in this appeal, and hence we do not address these topics further.

[5] CDTFA's Decision states that appellant holds a California seller's permit effective August 1, 2012. The July 22, 2016 NOD indicates that appellant holds a Certificate of Registration – Use Tax. Holders of such certificates are required to collect tax from purchasers and pay the tax in the same manner as retailers engaged in business in this state. (Cal. Code Regs., tit. 18, § 1684(e).)

5. CDTFA conducted an audit of appellant for the period August 1, 2012, through June 30, 2015, and found that appellant was liable for use tax on unreported withdrawals of Prolieve System kits from its resale inventory.
6. CDTFA issued to appellant an NOD dated July 22, 2016, for use tax of $27,051.94, plus applicable interest. Appellant made a series of payments and filed a timely claim for refund. In a Decision dated July 25, 2019, CDTFA denied appellant's claim for refund. This appeal followed.

DISCUSSION

Issue - Whether a refund is warranted for use tax paid on appellant's withdrawal of TPP from its resale inventory.

Use tax applies to the storage, use, or other consumption of TPP purchased from any retailer for storage, use, or other consumption in this state, measured by the sales price, unless that use is specifically exempted or excluded by statute. (R&TC, §§ 6201, 6401.) It is presumed that TPP sold by any person for delivery in this state is sold for storage, use, or other consumption in this state until the contrary is established. (R&TC, § 6241.)

Exemptions from tax are strictly construed against the taxpayer, who has the burden of proving that it comes clearly within the terms authorizing the exemption. (*H. J. Heinz Co. v. State Board of Equalization* (1962) 209 Cal.App.2d 1.) R&TC section 6369 provides an exemption for sales and use of medicines, when those medicines are prescribed and sold or furnished under specified conditions for the treatment of a human being. R&TC section 6369(c)(2) and California Code of Regulations, title 18, section (Regulation) 1591(b)(2) explain that the term "medicines" also includes any "article . . . permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body." Regulation 1591(b)(2) further clarifies which permanently implanted articles are included in the definition of "medicines," including permanently implanted catheters, but not disposable urethral catheters.

Regulation 1591.1 generally explains the prescription medicines exemption as it relates to specific medical devices, appliances and related supplies. Regulation 1591.1 states that generally, sales of catheters are subject to tax in the same manner as other sales of TPP. However, sales of certain types of catheters specified in Regulation 1591.1(b)(4)(A) through (D)

are not subject to tax. Those types of catheters that qualify for the exemption are as follows: (A) intra-aortic balloon pump catheters and coronary angioplasty balloon catheters; (B) catheters which are permanently implanted in the human body and assist the functioning of a natural organ, artery, vein, or limb and remain or dissolve in the body; (C) catheters used for drainage purposes through which an artificial opening is created in the human body, when such catheters qualify as ostomy materials and related supplies; and (D) catheters or similar types of devices used for drainage purposes through natural openings in the human body to assist or replace the functioning of a natural part of the human body, and which are worn on or in the body of the user and qualify as prosthetic devices. (Cal. Code Regs., tit. 18, § 1591.1(b)(4).)

Appellant contends that the catheter component of the Prolieve System (Prolieve catheter) qualifies for the medicines exemption pursuant to R&TC section 6369 and Regulation 1591.1(b)(4). Appellant acknowledges that the Prolieve catheter does not specifically meet any of the descriptions of the catheters listed in Regulation 1591.1(b)(4)(A) through (D); however, appellant argues that the Prolieve catheter is analogous to an angioplasty balloon catheter, and therefore the Prolieve catheter should qualify as exempt because angioplasty balloon catheters meet the requirements for the exemption. In support, appellant points to similarities between Prolieve catheters and angioplasty balloon catheters, including that both relieve obstructions in a patient's body, both cause similarly improved clinical outcomes, both are removed from the patient's body following the respective treatments, and neither are classified as indwelling or drainage catheters. Appellant argues that both Prolieve catheters and angioplasty balloon catheters are implanted in the body and are approved by the U.S. FDA to mitigate, treat, or prevent disease, illness, or medical condition, and thus both types of catheters are distinguished from "general catheters," the sales of which are subject to tax in the same manner as sales of other TPP pursuant to Regulation 1591.1(b)(4).

Additionally, appellant asserts that the Prolieve System include related supplies that meet the definition of "related supplies" pursuant to Regulation 1591.1(b)(3).[6] Appellant states that

[6] Appellant's opening brief states that the related supplies "specifically fall into the definition of tax-exempt related supplies as noted in Regulation 1591.3 of the Sales and Use Tax Regulations, Article 7," and quotes language from Regulation 1591.1(b)(3). Regulation 1591.3 is titled "Vehicles for Physically Handicapped Persons" and solely pertains to an exemption for the sale or use of vehicles for handicapped persons and items and materials used to modify or repair those vehicles. Nothing in Regulation 1591.3 could potentially be relevant to the issue in the present case, and thus we conclude that appellant intended to cite to Regulation 1591.1(b)(3), not Regulation 1591.3.

the Prolieve System's supplies qualify for the exemption because they are "a necessary and integral part of the machine itself," and that in this instance the machine is the microwave generator that is part of the Prolieve System's microwave thermotherapy.

Sales of catheters are subject to tax in the same manner as other sales of TPP, unless the catheter qualifies as one of the specific types of catheters that are covered by the exemption under R&TC section 6369, as implemented by Regulations 1591 and 1591.1. There is no question that the Prolieve catheter does not meet the definitions of any of the catheters covered by the exemption pursuant to Regulation 1591.1(b)(4)(A) through (D). Specifically, Prolieve catheters are not any of the following: intra-aortic balloon pump catheters or coronary angioplasty balloon catheters; catheters permanently implanted in the human body; catheters used for drainage purposes through which an artificial opening is created in the human body (i.e., ostomy materials and related supplies); or catheters or similar types of devices used for drainage purposes through natural openings in the human body to assist or replace the functioning of a natural part of the human body, and which are worn on or in the body of the user and qualify as prosthetic devices. (Cal. Code Regs., tit. 18, § 1591.1(b)(4).) Furthermore, there is no evidence or argument that sales of Prolieve catheters otherwise qualify as exempt sales of medicines as provided in R&TC section 6369 and Regulation 1591. Hence, sales and use of the Prolieve catheters do not qualify for the exemption and are subject to tax in the same manner as other sales and use of TPP.

Given that Prolieve catheters are not covered by any of the definitions in Regulation 1591(b)(4), appellant's comparisons of the Prolieve catheters to angioplasty balloon catheters are unpersuasive. Because the plain language of the applicable regulation clearly does not extend to the Prolieve catheter, the similarities between a Prolieve catheter and an angioplasty balloon catheter are immaterial to our analysis.

Finally, appellant's contention about the applicability of Regulation 1591.1(b)(3) also does not succeed. Regulation 1591.1(b)(3) provides that R&TC section 6369's exemption extends to ostomy appliances, kidney dialysis machines, and their related supplies. The Prolieve System is not a kidney dialysis machine, and thus its related supplies are not a necessary and integral part of a kidney dialysis machine.

HOLDING

Appellant has not established that its use of catheters or related supplies is exempt from tax.

DISPOSITION

CDTFA's action in denying appellant's claim for refund is sustained.

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Suzanne B. Brown
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Suzanne B. Brown
Administrative Law Judge

We concur:

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Daniel Cho
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Daniel K. Cho
Administrative Law Judge

DocuSigned by:
3CADA62FB4864CB...
Andrew J. Kwee
Administrative Law Judge

Date Issued: 8/13/2020