

**OFFICE OF TAX APPEALS**  
**STATE OF CALIFORNIA**

In the Matter of the Appeal of: ) OTA Case No. 19075004  
**ANGIODYNAMICS, INC.** ) CDTFA Case ID 848477  
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**OPINION**

Representing the Parties:

For Appellant:	Jacob Bholat, Representative
For Respondent:	Amanda Jacobs, Tax Counsel III Scott Claremon, Tax Counsel IV Jason Parker, Chief of Headquarters Ops.

A. WONG, Administrative Law Judge: Pursuant to Revenue and Taxation Code (R&TC) section 6901, AngioDynamics, Inc. (appellant) appeals a decision issued by respondent California Department of Tax and Fee Administration (CDTFA)<sup>1</sup> denying appellant’s timely claim for refund of \$34,087.37 for the period July 1, 2011, through December 31, 2013 (claim period).

Office of Tax Appeals (OTA) Administrative Law Judges Andrew Wong, Nguyen Dang, and Josh Aldrich held an oral hearing for this matter on September 22, 2020.<sup>2</sup> At the conclusion of the oral hearing, the record was closed and this matter was submitted for decision.

**ISSUE**

Whether Port-a-Cath systems qualify as medicines.

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<sup>1</sup> Sales taxes were formerly administered by the State Board of Equalization (Board). In 2017, functions of Board relevant to this case were transferred to CDTFA. (Gov. Code, § 15570.22.) For ease of reference, when referring to acts or events that occurred before July 1, 2017, “CDTFA” shall refer to Board; and when referring to acts or events that occurred on or after July 1, 2017, “CDTFA” shall refer to CDTFA.

<sup>2</sup> Although the oral hearing was noticed for Cerritos, California, due to the coronavirus/COVID-19 pandemic, we conducted the oral hearing by videoconference with the parties’ consent.

FACTUAL FINDINGS

1. Appellant, an out-of-state corporation headquartered in New York, designs, manufactures, and sells medical products.
2. During the claim period, appellant remitted sales tax based on its gross receipts from sales of Port-a-Cath systems in California.
3. A Port-a-Cath system is an implanted article that provides repeated access to a blood vessel in persons who require frequent administration of intravenous fluids, nutritional supplements, blood, blood products, or medications, as well as withdrawal of blood samples for lab testing.
4. A Port-a-Cath system comprises two parts: (1) a port and (2) a narrow, flexible tube called a catheter.
5. The port is a small plastic or metal disc (about the size of a half-dollar) with a slightly raised rubber injection site made of resealable silicone material. The resealable silicone material can be punctured numerous times with a special needle. The port is implanted under the skin, usually in the chest or arm.
6. Attached to the base of the port is the catheter, which is inserted into a large blood vessel and can be used to deliver substances from the port into a person's bloodstream or to withdraw blood samples.
7. On October 16, 2014, appellant timely filed a claim for refund of \$34,715.55 for sales tax remitted during the claim period. Later, CDTFA and appellant agreed that only \$34,087.37 of the claimed amount related to sales of Port-a-Cath systems.
8. During the processing of this refund claim, on October 24, 2017, in a prior appeal, the members of the Board granted appellant's claim for refund of \$34,912.41 for remitted sales tax measured by the gross receipts from sales of Port-a-Cath systems in California for the period of January 1, 2009, through June 30, 2011.
9. Contrary to this prior result, in a Decision dated June 14, 2019, CDTFA denied appellant's claim for refund of \$34,087.37 (i.e., the refund claim at issue). This appeal followed.

## DISCUSSION

California imposes sales tax on a retailer measured by the gross receipts from the retail sale of tangible personal property in this state unless the sale is specifically exempted or excluded from taxation by statute. (R&TC, §§ 6012, 6051.) The gross receipts from the sale of medicines in this state are exempted from tax when prescribed, furnished, or sold under certain conditions. (R&TC, § 6369(a)(1)-(6); Cal. Code Regs., tit. 18, § 1591(d).)

Here, it is undisputed that appellant met those certain conditions, so we need not elaborate upon them here. The sole issue presented for our consideration is whether Port-a-Cath systems are “medicines” within the meaning of the Sales and Use Tax Law.

Generally, “medicines” means 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. (R&TC, § 6369(b); Cal. Code Regs., tit. 18, § 1591(b)(1).) Port-a-Cath systems do not qualify as medicines under this definition because they are not substances or preparations;<sup>3</sup> rather, they are categorized as “articles.” (See Cal. Code Regs., tit., 18, § 1591(b)(2).)

Only some articles qualify as medicines. “Medicines” do *not* include “[a]rticles that 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.” (R&TC, § 6369(b)(2).) However, “medicines” *do* include articles (other than dentures) 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. (R&TC, § 6369(c)(2).) An article is considered to be permanently implanted if its removal is not otherwise anticipated. (Cal. Code Regs., tit. 18, § 1591(b)(2).) Permanently implanted articles qualifying as “medicines” include, but are not limited to, permanently implanted artificial sphincters, testicular gel implants, and permanently implanted catheters. (*Ibid.*)

As most relevant here, California Code of Regulations, title 18, (Regulation) section 1591(b)(2) states, “Implantable articles that do *not* qualify as ‘permanently’ implanted medicines include ... Port-a-Cath systems used for drug infusion purposes.” (Italics added.)

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<sup>3</sup> Substances and preparations include, but are not limited to, drugs, antibiotics, aspirin, baby lotion, baby oil, baby powder, enema preparations, lubricating jelly, and vaccines. (Cal. Code Regs., tit. 18, § 1591(b)(1).)

Here, Regulation section 1591(b)(2) explicitly excludes Port-a-Cath systems from “medicines.” Where the plain language of a regulation is unambiguous, we need not inquire further to ascertain its meaning. (See *Desert Palace, Inc. v. Costa* (2003) 539 U.S. 90, 98.) Accordingly, we conclude that Port-a-Cath systems do not qualify as medicines and the sale of Port-a-Cath systems are subject to sales tax.

On appeal, appellant contends that the sale of Port-a-Cath systems are exempt sales of medicines despite the explicit reference to them in Regulation section 1591(b)(2). Appellant offers four arguments: (1) the Board previously and correctly decided that Port-a-Cath systems qualify as medicines despite Regulation section 1591(b)(2), and we should follow the Board’s decision here and guide CDTFA towards following it in the future; (2) we should ignore or limit the explicit reference to Port-a-Cath systems in Regulation section 1591(b)(2); (3) we should invalidate the explicit reference to Port-a-Cath systems in Regulation section 1591(b)(2); and (4) we should determine that Port-a-Cath systems qualify as medicines under a separate regulation, Regulation section 1591.1(b)(4)(B).

#### Appellant’s First Argument: Follow and Guide

First, appellant contends that the Board correctly decided that Port-a-Cath systems were medicines when granting appellant’s prior claim for refund in October 2017; however, CDTFA subsequently ignored the Board’s authoritative action when it wrongfully denied appellant’s current claim for refund by Decision dated June 14, 2019. Accordingly, appellant contends that we must follow the Board’s October 2017 decision here and compel CDTFA to follow it going forward. In support, appellant cites to Government Code section 15570.22 for the proposition that the Board’s October 2017 decision continues in force to this day and must be enforced in this case and all future ones involving Port-a-Cath systems.

A decision may not be expressly relied upon as precedent unless it is designated as a precedent decision by the agency. (Gov. Code, § 11425.60(a).) “All laws prescribing the duties, powers, and responsibilities of the [B]oard to which [CDTFA] succeeds, together with all lawful rules and regulations established under those laws, are expressly continued in force....” (Gov. Code, § 15570.22.)

Here, nothing in the record indicates that the Board designated its October 24, 2017 decision as precedential; thus, while we respect the Board’s authority to make that decision at that time, we are not compelled to follow or “enforce” it in the appeal before us.

Instead, in this appeal, we have concluded that Regulation section 1591(b)(2) plainly excludes Port-a-Cath systems from the category of permanently implanted articles. Therefore, they do not qualify as medicines. And rather than undercutting that conclusion, as appellant contends, Government Code section 15570.22 supports it, stating that all lawful regulations—which *includes* Regulation section 1591(b)(2)—expressly continue in force. The current version of Regulation section 1591(b)(2), which states that Port-a-Cath systems are not permanently implanted medicines, was also in force when the Board made its October 24, 2017 decision, and neither the Board nor CDTFA have since amended the regulation to delete that language. Regulation section 1591(b)(2)'s disqualification of Port-a-Cath systems from the category of medicines continues in force as of the date of this Opinion. Therefore, we conclude that appellant's first argument lacks merit.

#### Appellant's Second Argument: Ignore or Limit

Second, appellant argues that we must ignore Regulation section 1591(b)(2)'s specific statement that Port-a-Cath systems do not qualify as medicines because, at the time that language was promulgated, Port-a-Cath systems were only temporarily implanted. Appellant contends that, now, with advances in technology, Port-a-Cath systems are permanently implanted and the specific reference to them in Regulation section 1591(b)(2) should be ignored or limited to apply only to temporarily implanted Port-a-Cath systems (not the permanently implanted ones that are at issue).

In support of this argument, appellant notes that the word “permanently” is presented in quotation marks in the last sentence of Regulation section 1591(b)(2) (i.e., the sentence stating that Port-a-Cath systems do not qualify as “permanently” implanted medicines). Appellant contends that the quotation marks are there for emphasis; that is, to heighten the contrast between Port-a-Cath systems, which were only *temporarily* implanted at the time this sentence was promulgated, and other “permanently” implanted articles that qualified as medicines.

If we were to ignore or limit that specific reference, appellant further argues that Port-a-Cath systems would qualify as medicines because they would then satisfy the two key elements

of a medicine established by Regulation section 1591(b)(2): (1) they are “permanently” implanted; and (2) they assist the functioning of a vein or artery.<sup>4</sup>

“A regulation adopted by an administrative agency pursuant to its delegated rulemaking authority has the force and effect of law.” (*California Teachers Assn. v. California Com. on Teacher Credentialing* (2003) 111 Cal.App.4th 1001, 1008.) Agencies granted power to make quasi-legislative rules are truly making law, so their quasi-legislative rules have the dignity of statutes. (*New Cingular Wireless PCS, LLC v. Public Utilities Com.* (2016) 246 Cal.App.4th 784, 808.) The Board was permitted to prescribe, adopt, and enforce regulations relating to the administration and enforcement of the Sales and Use Tax Law. (R&TC, § 7051; see also *Henry’s Restaurant of Pomona, Inc. v. State Bd. of Equalization* (1973) 30 Cal.App.3d 1009, 1020.) CDTFA is the successor to the Board with respect to the administration of the Sales and Use Tax Law. (Gov. Code, § 15570.22.) Accordingly, CDTFA’s regulations under the Sales and Use Tax Law have the dignity of statutes, and OTA cannot refuse to follow a regulation based on alleged invalidity. (See *Appeal of Talavera*, 2020-OTA-022P.)

The rules that govern interpretation of statutes also govern interpretation of administrative regulations. (*Berkeley Hillside Preservation v. City of Berkeley* (2015) 60 Cal.4th 1086, 1097.) Before an administrative agency can interpret an administrative regulation, interpretation must first appear necessary. (See *Cullinan v. McColgan* (1947) 80 Cal.App.2d 976, 979.) Where the language of an administrative regulation is plain and unambiguous, there is no need to resort to interpretation. (See *ibid.*)

Exemptions from tax are strictly construed against the taxpayer. (*H. J. Heinz Co. v. State Bd. of Equalization* (1962) 209 Cal.App.2d 1, 4.) The party claiming an exemption bears the burden of showing that it clearly comes within the terms authorizing exemption. (*Ibid.*) Any doubt must be resolved against the right to an exemption. (*Associated Beverage Co. v. State Bd. of Equalization* (1990) 224 Cal.App.3d 192, 211.)

Here, Regulation section 1591(b)(2) explicitly excludes Port-a-Cath systems from the category of permanently implanted articles/medicines and has the force and effect of law, as well

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<sup>4</sup> In support of this argument, appellant lists several permanently implanted medical products that were initially disqualified as medicines by Board staff since 2000, but that the five-member Board subsequently exempted as sales of medicines under Regulation section 1591(b)(2) pursuant to their then-existing rulemaking authority. Appellant contends that, but for the transfer of the Board’s administrative responsibilities over sales and use taxes to CDTFA in 2017 (*ante*, fn. 1), Port-a-Cath systems would have eventually joined that list. This aspect of appellant’s second argument is mere speculation, so we decline to address it further.

as the dignity of a statute. We cannot ignore the regulation’s plain language and CDTFA’s authority to exclude Port-a-Cath systems from the definition of medicines. Furthermore, the plain and unambiguous language of Regulation section 1591(b)(2) does not distinguish between temporarily or permanently implanted Port-a-Cath systems when excluding them from the definition of permanently implanted medicines. Consequently, we need not determine whether Port-a-Cath systems would otherwise satisfy the elements mentioned in Regulation section 1591(b)(2) and qualify as medicines on that basis. Therefore, we conclude that appellant’s second argument lacks merit.

Appellant’s Third Argument: Invalidate

Third, appellant argues that Regulation section 1591(b)(2) is invalid because, in disqualifying Port-a-Cath systems as medicines, the regulation goes beyond R&TC section 6369(c)(2), which never disqualifies or even references Port-a-Cath systems. Appellant contends that we must resolve this alleged conflict in favor of the R&TC, and essentially invalidate the reference to Port-a-Cath systems in Regulation section 1591(b)(2).

State agencies granted substantive rulemaking power are truly making law, so their quasi-legislative regulations have the dignity of statutes. (*Yamaha Corp. of America v. State. Bd. of Equalization* (1998) 19 Cal.4th 1, 10.) In California, only a court may declare a quasi-legislative regulation that has been formally promulgated by a state agency to be invalid. (See *Appeal of Talavera*, 2020-OTA-022P (citing Gov. Code, § 11350(b)).) OTA is not a court. (*Appeal of Talavera*, 2020-OTA-022P (citing Gov. Code, § 15672).) Therefore, OTA does not have the authority to declare Regulation section 1591(b)(2) to be invalid, to refuse to follow it on that basis, or to resolve any alleged conflict between R&TC section 6369(c)(2) and Regulation section 1591(b)(2).<sup>5</sup> We conclude that appellant’s third argument lacks merit.

Appellant’s Fourth Argument: Interpret

Fourth, appellant contends that Port-a-Cath systems qualify as medicines under Regulation section 1591.1(b)(4)(B). Regulation section 1591.1(b)(4)(B) states that *catheters* that are permanently implanted and assist the functioning of an artery or vein and remain and dissolve in the body are not subject to tax. Appellant either contends that Port-a-Cath systems, in

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<sup>5</sup> CDTFA, not OTA, is imbued with the power to revise its regulations. (See R&TC, § 7051.)

and of themselves, are catheters or asks us to interpret the word “catheters” in Regulation section 1591.1(b)(4)(B) to include Port-a-Cath systems.

R&TC section 6369(b)(2) states that “medicines” does not include an “article or the component parts ... thereof.” That is, neither an article nor its component parts qualify as a medicine. Regulation section 1591(b)(2) specifically states that Port-a-Cath systems used for drug infusion purposes are articles that do not qualify as a medicine. Per R&TC section 6369(b)(2), the component parts of Port-a-Cath systems also do not qualify as medicines, and the sale of such are subject to tax.


Here, the Port-a-Cath system is not a catheter and the sale of a Port-a-Cath system is not exempt from tax under Regulation section 1591.1(b)(4)(B). Instead, a catheter is only a component part of a Port-a-Cath system, with the other part being a port. Together, they compose the Port-a-Cath system, which does not qualify as a medicine under Regulation section 1591(b)(2). And, per R&TC section 6369(b)(2), the sale of a Port-a-Cath system’s two parts, a port and a catheter, is subject to tax as component parts of the whole. Accordingly, we conclude that appellant’s fourth and final argument is without merit.

#### HOLDING

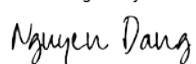
Port-a-Cath systems do not qualify as medicines.


#### DISPOSITION

We sustain CDTFA’s action in denying appellant’s claim for refund.

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Andrew Wong  
Administrative Law Judge

We concur:

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Nguyen Dang  
Administrative Law Judge

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Josh Aldrich  
Administrative Law Judge

Date Issued: 12/17/2020