

ST 24-0013-GIL 03/22/2024 MEDICAL DEVICES

A medical appliance is an item that directly substitutes for a malfunctioning part of the human body. Products that qualify as medical appliances are taxed at a lower State tax rate of 1% plus any applicable local taxes. 35 ILCS 120/2-10; 35 ILCS 120/14; 86 Ill. Adm. Code 130.311. (This is a GIL).

March 22, 2024

PERSON
COMPANY
ADDRESS

Email: EMAIL

Dear XXXX:

This letter is in response to your letter dated January 17, 2024, in which you requested information. The Department issues two types of letter rulings. Private Letter Rulings (“PLRs”) are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department’s regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter (“GIL”) is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. 2 Ill. Adm. Code 1200.120. You may access our website at <https://tax.illinois.gov/> to review regulations, letter rulings and other types of information relevant to your inquiry.

Whether to issue a private letter ruling in response to a letter ruling request is within the discretion of the Department. The Department will respond to all requests for private letter rulings either by issuance of a ruling or by a letter explaining that the request for ruling will not be honored. 2 Ill. Adm. Code 1200.110(a)(4). A private letter ruling will not be issued if the Department’s regulations are dispositive of the subject of the request and the request does not meet the requirements under 2 Ill. Adm. Code 200.110(b)(1)-(8). The Department determined not to issue a Private Letter Ruling in response to your request. However, the Department is issuing a General Information Letter to help address your questions. In your letter you have stated and made inquiry as follows:

Dear Illinois Department of Revenue:

Please accept this memorandum as a request for a Private Letter Ruling regarding the application of Illinois sales and use tax to the below described fact pattern.

I. BACKGROUND

COMPANY is a medical device company headquartered in CITY, STATE that specializes in the treatment of obstructive sleep apnea (“OSA”). Specifically, COMPANY’s treatment of OSA involves their NAME procedure.

OSA is chronic sleep disorder where a person’s upper airway experiences a partial or complete collapse and results in disrupted sleep and daytime fatigue. The most common treatment for OSA is the continuous positive airway pressure (“CPAP”) device. When CPAP treatment is ineffective, upper airway surgery is the next option. Uvulopalatopharyngoplasty (“UPPP”) has been an established surgical treatment of OSA but only treats airway obstructions at the level of the palate and therefore has limited efficacy. COMPANY developed the NAME procedure as a less invasive way to treat airway obstructions at the level of the tongue base. It can be used as a standalone intervention or combined with UPPP to treat all levels of the airway.

The NAME procedure involves an integrated set of instruments and implants designed to treat different causes of OSA. These instruments and implants are the SYSTEM and TOOL which treat causes of OSA by performing hyoid suspension to the mandible and/or tongue suspension. COMPANY sells these components to medical practitioners, not directly to patients. Also, a physician's prescription is necessary for a patient to receive the NAME procedure. The SYSTEM is an FDA 510(k) cleared Class II Device (the FDA has deemed the device safe and effective for OSA treatment) which is reimbursable by the Centers for Medicare and Medicaid Services (“CMS”) for the treatment of OSA. The TOOL is a Class I FDA-registered device.

The components of the NAME procedure, The SYSTEM and TOOL, are sold as a kit although COMPANY itemizes the component charges on their invoices. The SYSTEM is sold for \$2,625.00, while the TOOL is sold for \$275.00. Occasionally, COMPANY will send their customers an additional tool kit for adjustments or removal of The SYSTEM. The TOOL is designed and used strictly for the NAME procedure and is not reusable. The TOOL does not remain in the body, so by itself, it is not a prosthetic device. But there is currently no other instrument available to substitute for the TOOL. It is COMPANY’s position that the TOOL’s value is immaterial compared to the overall cost of the kit. Most of the value of these components is derived from the SYSTEM which includes the actual implants that perform the hyoid or tongue suspension. Therefore, the two components are indivisible since the SYSTEM cannot be readily implanted without use of the TOOL tool, and said tool has no other utility other than to implant the SYSTEM.

The SYSTEM provides a proprietary suspension and bone anchoring procedure that is easily adjusted for the effective treatment of treating OSA. It is used almost exclusively for performing hyomandibular suspension with tongue suspension performing only occasional (primarily in pediatric patients).

The SYSTEM is implanted in a patient through small incisions in their inferior mandible. Another small incision is made over the patient’s hyoid bone. The hyoid bone is stabilized using a tracheal hook. The TOOL passes around the hyoid bone to thread a suspension line. This suspension line tails around the hyoid bone when the TOOL is backed out leaving a looped suture above the hyoid bone. The looped suture is secured to the hyoid bone using a girth hitch knot. The bone anchors have an eyelet through

which the suspension line is threaded. This process is performed twice in a bilateral fashion from the midline of the mandible resulting in two suspension lines that are tensioned to suspend the hyoid bone and secured by tightening a lock screw in the bone anchors. As needed, a suture loop can also be used to prevent a patient's tongue from blocking their airway.

Unlike UPPP, NAME allows adjustments to the positioning of the hyoid bone or tongue based on the severity of a patient's upper airway collapse. Also, this procedure can be reversed, and the SYSTEM can be removed.

II. ISSUE

1. Does COMPANY's sales of the SYSTEM qualify for the state's medical device reduced tax rate?
2. Does COMPANY's sales of the TOOL qualify for the for the state's medical device reduced tax rate?
3. Please confirm that local Illinois sales tax rates apply regardless of the reduced state sales tax rate.
4. Do the components of COMPANY's NAME procedure meet the state's definition of a "medical device"?
 - a. What evidence is required for it to be considered as prescribed?
5. If your agency determines The SYSTEM meets the reduced sales tax rate criteria, but The TOOL does not, would the full sales tax only apply to The TOOL? Or would the entire sale be considered taxable at the full rate?
 - a. Does the immaterial value of The TOOL tool affect the state's taxability position of COMPANY's kit sales?
 - b. What is the state's position about the true object test of the NAME procedure's components?

Please let us know if you have any questions or need additional information to make a decision. I can be reached at PHONE, but my preference is email correspondence (EMAIL).

Thank you for your consideration and assistance.

DEPARTMENT'S RESPONSE:

Medical devices are subject to 1% tax under the Retailers' Occupation Tax Act. 35 ILCS 120/2-10. Tangible personal property that does not qualify for the low rate of tax is taxed at the rate of 6.25% of the gross receipts from sales. 35 ILCS 120/2-10. This tax is in addition to any applicable local taxes. 35 ILCS 120/14. Section 130.311 pertaining to Drugs, Medicines, Medical Appliances and Grooming and Hygiene Products provides as follows:

- e) Medical Appliances: A medical appliance is an item that is used to directly substitute for a malfunctioning part of the human body.
 - 1) For purposes of this Section, an item that becomes part of the human body by substituting for any part of the body that is lost or diminished

because of congenital defects, trauma, infection, tumors, or disease is considered a medical appliance. Examples of medical appliances that will qualify the product for the low rate of tax include, but are not limited to:

- A) breast implants that restore breasts after removal due to cancer or for preventative, medical reasons;
- B) heart pacemakers;
- C) artificial limbs;
- D) dental prosthetics;
- E) crutches and orthopedic braces;
- F) dialysis machines (including the dialyzer);
- G) wheelchairs;
- H) mastectomy forms and bras;
- I) mobility scooters; and
- J) **sleep apnea devices.**

86 Ill. Adm. Code 130.311(e)(1) (emphasis added).

Please note that “other medical tools, devices, and equipment such as x-ray machines, laboratory equipment, and surgical instruments that may be used in the treatment of patients but that do not directly substitute for a malfunctioning part of the human body do not qualify as medical appliances.” 86 Ill. Adm. Code 130.311(e)(5). It appears that the TOOLS may be classified as medical tools or surgical instruments. With respect to kits, the Department will consider the selling price of the entire kit to be taxable at the reduced rate when the value of the medical appliances in the kit is more than half of the total selling price of the kit. See 86 Ill. Adm. Code 130.311(e)(5). It is unclear in your request what exactly is included in each kit sold. To determine whether the value of the medical appliances in the kit is more than half of the total selling price of the kit, the value of each item in the kit must be known and considered. If the value of the items in the kit that do not qualify as medical appliances constitutes more than half of the total selling price of the kit, the selling price of the entire kit will be subject to the 6.25% tax rate.

Local governments generally do not have authority to impose tax on the sale of tangible personal property taxed at the 1% rate under the Retailers’ Occupation Tax Act such as medical appliances. See e.g., 65 ILCS 5/8-11-1 (Home Rule Municipal Retailers’ Occupation Tax Act). However, two local taxing jurisdictions, the Regional Transportation Authority (“RTA”) and the Metro East Mass Transit District (“MED”), do have the authority to impose additional tax on 1% rate items. See 70 ILCS 3615/4.03(e); 70 ILCS 3610/5.01(b).

The RTA tax rate in Cook County on sales of tangible personal property taxed at the 1% rate under the Retailers’ Occupation Tax Act is 1.25% and 1% for taxable sales of other tangible personal property. The RTA tax rate in DuPage, Kane, Lake, McHenry, and Will counties is 0.75% on all taxable sales of tangible personal property. 70 ILCS 3615/4.03(e). The MED tax rate is 0.75% on all tangible personal property sold in MED locations in St. Clair County and 0.25% on all tangible personal property sold in MED locations in Madison County. 70 ILCS 3610/5.01(b). For the sake of differentiating these taxes from local taxes imposed by other jurisdictions, we will refer to them in this letter as “transportation district taxes”.

If the items described in this letter are taxed at the rate of medical appliances, then they are

COMPANY
Page 5
March 22, 2024

subject to the low rate of tax (1% State tax), plus any applicable transportation district taxes. If this is not the case, the items in this letter are subject to the high rate of tax (6.25% State tax), plus any local tax (e.g., Home Rule Municipal Retailers' Occupation Tax), including transportation district taxes, at the general merchandise rate.

I hope this information is helpful. If you have further questions related to the Illinois sales tax laws, please visit our website at <https://tax.illinois.gov> or contact the Department's Taxpayer Information Division at (217) 782-3336.

Very truly yours,

Katarzyna Kowalska
Associate Counsel

KK:slc