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June 26, 2020

VIA E-MAIL

Craig Johnson
Executive Director
Streamlined Sales Tax Governing Board
100 Majestic Drive, Suite 400
Westby, WI 54667

Re: Interpretation – Definition Request

Dear Mr. Johnson:

The attached is being submitted on behalf of Medtonic USA, Inc. If you have any questions or need any additional information, please contact the undersigned.

Very truly yours,

Richard Nielsen

Richard E. Nielsen

Attachment



100 Majestic Drive, Suite 400 • Westby, WI 54667

Interpretation – Definition Request

Provide the name(s) and contact information of the state or parties submitting the Request.

Date Request is submitted: 6/26/2020

Name of Person(s) submitting request: Richard Nielsen for Medronic USA, Inc.

Contact Person: Richard E. Nielsen of Pillsbury Winthrop Shaw Pittman LLP

Address: Four Embarcadero Center, Fl. 22, San Francisco, CA 94111

Phone: 415-983-1964 **Email:** richard.nielsen@pillsburylaw.com

1. Agreement Section(s), Rules or Tax Administration Practice(s) involved:

Appendix C, Part II, Product Definitions, Prosthetic Device (pp. 117-118); Appendix L, ECG Monitor - Implanted

2. Issue:

Whether implanted (insertable) cardiac (ECG) monitors meet the SSUTA definition of a prosthetic device?

3. Statement of Background Facts (Provide a detailed description of the issue and supporting facts.):

See attached.

4. Proposed Interpretation:

Clarify whether insertable cardiac (ECG) monitors qualify as a prosthetic device.

5. Is expedited consideration requested? ☒ NO ☐ YES If yes, please explain: [Click here to enter text.](#)

A request for interpretation or definition normally requires a minimum 60-day comment period. The comment period may be shortened to 10 days if the Committee grants a request for expedited consideration. See Governing Board Rule 902(#) and (H).

Submit completed form to:

Craig Johnson, Executive Director
Streamlined Sales Tax Governing Board
100 Majestic Dr., Suite 400
Westby, WI 54667

Email: Craig.Johnson@SSTGB.org
Phone: 608-634-6160
www.streamlinedsalestax.org

Compliance Review and Interpretations Committee Meeting Schedule

The Compliance Review and Interpretations Committee meets by teleconference at 10:00 am central every other Thursday. Its schedule can be found at www.streamlinedsalestax.org under the meeting calendar.

Attachment to Interpretation – Definition Request

3. Statement of Background Facts (Provide a detailed description of the issue and supporting facts.):

Medtronic USA, Inc. (“Medtronic”) seeks an interpretation opinion of the definition of a prosthetic device under the Streamlined Sales and Use Tax Agreement (“SSUTA”) pursuant to Rule 902 on the issue set forth below. Medtronic has received numerous correspondence from its customers in various states disputing the collection of tax on its products described below claiming the products are exempt prosthetic devices. Medtronic has sought and obtained conflicting rulings, audit treatment or informal advice from numerous member states including Washington, Nevada, West Virginia and New Jersey. Additionally, Medtronic is faced with competitors receiving disparate treatment and selling similar products without charging their customers tax.

A. Statement of Issue

Whether implanted cardiac (ECG) monitors meet the SSUTA definition of a prosthetic device?

B. Statement of Facts

Medtronic manufactures the REVEAL XT or REVEAL LINQ¹ Insertable Cardiac Monitor (collectively “RICM”). The RICM is a long-term heart monitoring device designed to help a doctor diagnose and treat irregular heartbeats. It is a minimally invasive heart monitor that is just inserted under the skin of the chest in a simple outpatient procedure. It requires no wires or patches on the outside of the body. The battery is designed to last for up to three years. The RICM keeps a patient connected to their doctor with continuous heart monitoring. It monitors the heart’s activity and records an abnormal rhythm in the form of an electrocardiogram (ECG) that is then transmitted to their physician for review.²

The RICM is used with patients that experience infrequent fainting episodes. The RICM monitors the patient’s heart to help doctors determine whether the unexplained fainting is heart related. The RICM records heart rhythms automatically or when the patient uses the hand-held activator.

Medtronic describes the RICM product as follows:

- a. “The RICM captures the ECG you need to make informed decisions about your syncope patients and those who experience transient symptoms that may suggest a cardiac arrhythmia”
- b. “May detect the presence of AT/AF, including asymptomatic episodes
Monitors AT/AF burden to assess whether medical treatment is necessary or should be adjusted

¹ LINQ is the new version of the XT. They are the same product but LINQ is smaller and easier to implant.

² <https://www.medtronic.com/us-en/patients/treatments-therapies/heart-monitors/our-monitors/reveal-xt.html>

Monitors ventricular rhythm during atrial arrhythmias to assess the efficacy of rate control therapy”

- c. “The RICM is an implantable patient activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

PRODUCT DETAILS

IMPLANT PROCEDURE

- Atrial tachyarrhythmia/atrial fibrillation (AT/AF)
 - Ventricular tachyarrhythmia (VT)
 - Fast ventricular tachyarrhythmia (FVT)
 - Bradyarrhythmias
 - Asystole
 - May detect the presence of AT/AF, including asymptomatic episodes
 - Monitors AT/AF burden to assess whether medical treatment is necessary or should be adjusted
 - Monitors ventricular rhythm during atrial arrhythmias to assess the efficacy of rate control therapy
 - patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
 - patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia.”
- d. “The RICM is placed under the skin in the upper chest area
- Slim-shaped, leadless device simplifies insertion
 - Easy access to diagnostic data without an in-office clinic visit – optimizes scheduling and treatment
 - Data may be transmitted immediately after patient-marked event or at scheduled intervals”

C. Summary of Law

Appendix C, Library of Definitions, Part II Product Definitions, within the health care category, sets forth the following definition:

“**Prosthetic device**” means a replacement, corrective, or supportive device including repair and replacement parts for same worn on or in the body to:

- A. Artificially replace a missing portion of the body;
- B. Prevent or correct physical deformity or malfunction; or
- C. Support a weak or deformed portion of the body.³

³ A member state may limit the application of this definition by requiring a “prescription,” or limit an exemption based on Medicare or Medicaid payments or reimbursements.

Appendix L, Health Care Item List, lists ECG Monitor – Implanted, with no description and indicates under Workgroup column: “Not Defined—See Disclosed Practice 7.”⁴

Some member states in their taxability matrixes under medical products 7.2 lists “ECG Monitors – Implanted” as prosthetic devices within the SSUTA defined term⁵ whereas others do not indicate a position notwithstanding listing the product⁶.

D. Analysis

Other than the authority mentioned above, there is a paucity of authority concerning the sales tax treatment of insertable (implantable) heart monitors. There are exemptions provided for durable medical equipment for home use and prosthetic devices. The primary distinction between the two categories is that prosthetic devices are worn on or in the body whereas durable equipment may not be worn on the body. N.J. Admin. Code 18:24-37.7 lists apnea monitors worn on the body as an example of exempt prosthetic devices. Apnea monitors detect the cessation of breathing (apnea) in infants and adults who are at risk of respiratory failure and alert the parent or attendant to the condition.⁷ As noted in the product description above, the RICM performs similar monitoring functions with respect to a patient’s heart. New Jersey specifically lists implantable ECG monitors as prosthetic devices in its taxability matrix.⁸ As mentioned above, other SSUTA states (Washington, Nevada and West Virginia) have concluded that implanted ECG monitors do not qualify as a prosthetic device because they do not support, replace or correct a portion of the body.

E. Conclusion

Medtronic is faced with conflicting rulings and classifications of its RICM product by member states. Further, customers face conflicting taxability treatment as some sellers of similar products are not charging tax. Medtronic customers have sought refunds. Medtronic seeks an interpretive ruling as to whether implantable ECG (cardiac) devices qualify within the SSUTA definition of a prosthetic device.

⁴ Of note, Appendix L lists Apnea Monitors and EEG items as durable medical equipment (items not worn on the body or implanted).

⁵ See New Jersey matrix 7.2r. (copy attached).

⁶ See Ohio matrix 7.2r.

⁷ https://www.who.int/medical_devices/innovation/apnea_monitor.pdf

⁸ See Fn. 5.

Medical Products 7.2.h	Denture adhesive				
Medical Products 7.2.i	Dialysis Bags - Peritoneal Dialysis Drain				
Medical Products 7.2.j	Dialyzers - Single Use (A dialyzer is an artificial kidney designed to provide controllable transfer of solutes and water across a semi permeable membrane separating flowing blood and dialysate streams. The transfer processes are diffusion (dialysis) and convection (ultrafiltration). There are three basic dialyzer designs: coil, parallel plate, and hollow fiber configurations. Filter that is incorporated in machine.)	X			Prosthetic device
Medical Products 7.2.k	Dressings - Compression - Non Medicated (Ace Bandages)	X			Prosthetic device
Medical Products 7.2.l	Dressings - Elastic - Non Medicated (Non-Ace bandages to hold dressings)	X			Prosthetic device
Medical Products 7.2.m	Dressings - Gauze Wraps (Tube gauze, Gauze Wraps)				
Medical Products 7.2.n	Dressings - General (Pads, sponges, tapes and adherents, elastic, compression, gauze)				
Medical Products 7.2.o	Dressings - Non-Medicated (Dressings containing a substance which is neither a RX or OTC drug)				
Medical Products 7.2.p	Dressings - Wound Care - Skin Barrier Products (Sprays, cream)				
Medical Products 7.2.q	Eating utensils - Adjustable				
Medical Products 7.2.r	ECG Monitor - Implanted	X			Prosthetic device
Medical Products 7.2.s	Fever thermometers - Disposable/SPU				
Medical Products 7.2.t	Gases - Non-Medical Grade		X	N.J.S.A. 54:32B-8.7	
Medical Products 7.2.u	Gases - Tanks for (Empty - Tanks only)				
Medical Products 7.2.v	Glucose for Insulin Reactions (Tablets, liquid)	X			Drug
Medical Products 7.2.w	Infuser Bags (Pressure Infuser bags - used to administer intravenous fluids under pressure at any angle to patients in pre-hospital or emergency room settings - Disposable)				
Medical Products 7.2.x	IV Therapy arm boards-Disposable				
Medical Products 7.2.y	IV Therapy Tourniquets - SPU (Disposable)				
Medical Products 7.2.z	Laboratory equipment (Microscopes, incubators, refrigerators, centrifuges)				