March 27, 2020

Medtronic, Inc.
Nancy Cameron
Senior Principal Regulatory Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K192389
Trade/Device Name: TYRX Absorbable Antibacterial Envelope (medium), TYRX Absorbable Antibacterial Envelope (large)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 2, 2020
Received: March 3, 2020

Dear Nancy Cameron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Hetal Odobasic
Assistant Director
Implantable Electrophysiology Devices Team
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
TBD K192389

Device Name
TYRX Absorbable Antibacterial Envelope

Indications for Use *(Describe)*
The envelope is intended to hold a pacemaker pulse generator or defibrillator securely in order to provide a stable environment when implanted in the body. The envelope contains the antimicrobial agents rifampin and minocycline, which have been shown to reduce infection in an in vivo model of bacterial challenge following surgical implantation of the generator or defibrillator. The envelope is intended to be used in conjunction with pacemakers and implantable defibrillators.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared:	28 August 2019
510(k) Owner / Address:	Medtronic, Inc. Cardiac Rhythm and Heart Failure (CRHF) 8200 Coral Sea St. NE Mounds View, MN 55112
Contact Person:	Primary Contact: Nancy Cameron Senior Principal Regulatory Affairs Specialist Medtronic Cardiac Rhythm Heart Failure 763.526.2355 *nancy.e.cameron@medtronic.com* Secondary Contact: Wendy Saunders Regulatory Affairs Director Medtronic Cardiac Rhythm Heart Failure 763.526.8134 wendy.a.saunders@medtronic.com
Submission Type:	Traditional 510(k): Shelf Life Extension
Device Trade Name:	TYRX™ Absorbable Antibacterial Envelope
Device Common Name:	Surgical Mesh
Regulation Number:	CFR 878.3300
Product Code:	FTL
Classification:	Class II
Classification Panel:	Cardiovascular
Special Controls:	None
Predicate Device:	TYRX™ Absorbable Antibacterial Envelope, K180030

Device Description

TYRX™ Absorbable Antibacterial Envelope (TYRX Envelope, or the envelope) is a sterile prosthesis comprised of two components; an absorbable substrate mesh, and an absorbable tyrosine based polyarylate polymer containing the antimicrobial agents, rifampin and minocycline, and is designed to hold a Cardiovascular Implantable Electronic Devices, CIED, (pacemaker or Implantable Cardioverter Defibrillator, ICD), securely to create a stable environment when the device is implanted in the body.

The TYRX Envelope is constructed of multifilament knitted mesh composed of glycolide, caprolactone, and trimethylene carbonate polymer, which is coated with an absorbable polyarylate polymer containing the drug substances rifampin and minocycline.

Like its predicate, the TYRX Envelope is supplied in two sizes, a 2.5 in. x 2.7 in. pacemaker size (Medium), and a 2.9 in. x 3.3 in. ICD size (Large). Details for the TYRX Envelopes are provided below.

Description of Device/ Part Number	Label Claim
TYRX Absorbable Antibacterial Envelope (Medium) Product ID: CMRM6122	5.1 mg Minocycline 8.0 mg Rifampin
TYRX Absorbable Antibacterial Envelope (Large) Product ID: CMRM6133	7.6 mg Minocycline 11.9 mg Rifampin

Indications for Use

There are no changes to the Indications for Use as a result of this submission. The Indications for Use are provided below:

> The envelope is intended to hold a pacemaker pulse generator or defibrillator securely in order to create a stable environment when implanted in the body. The envelope contains the antimicrobial agents, rifampin and minocycline, which have been shown to reduce infection in an *in vivo* model of bacterial challenge following surgical implantation of a pacemaker or defibrillator. The envelope is intended to be used in conjunction with pacemakers or defibrillators.

Technological Characteristics

TYRX Envelope is a biocompatible, sterile device intended to hold a pacemaker or defibrillator securely in the surgically created tissue pocket in order to create a stable environment for the pacemaker or defibrillator when implanted in the body. The TYRX Envelope is identical to its predicate device, cleared under K180030. The further extension of product shelf life presented in this submission does not impact the technical characteristics of the device as compared to the predicate device.

Summary of Testing

Extension of the TYRX Envelope shelf life is supported by stability study data collected per ICH guidelines. Results of this study demonstrate the TYRX Envelope, both medium and large size, continue to meet all product requirements through the proposed shelf life. There are no changes

to the finished product TYRX Envelope analytical testing requirements as a result of the modifications described in this submission. The extended shelf life TYRX Envelope design, materials, mechanism of action, patient contact and intended use are the same as the predicate device.

Substantial Equivalence

Substantial equivalence of the TYRX Envelope with the proposed shelf life is based on ICH stability studies conducted using the dual foil pouch package with desiccant. Other minor manufacturing changes have been incorporated per Quality System processes. There are no changes to the finished product TYRX Envelope analytical testing requirements, design, materials, mechanism of action, patient contact or intended use associated with the extended shelf life. The individual and cumulative impact of these changes does not alter the risk profile of the TYRX Envelopes. The modified device meets the same finished goods acceptance criteria, using the same analytical test methodologies, as the currently marketed device. Therefore, the TYRX Envelope device, as modified with extended shelf life, is substantially equivalent to the predicate device.

Conclusion

The TYRX Absorbable Antibacterial Envelope, as modified, is substantially equivalent to the predicate device.

Overall, these modifications do not affect the intended use of the device or alter the fundamental scientific technology. There are no changes to the physical design, principles of operation, or mechanism of action of the current TYRX Envelope.