April 24, 2018

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

Re: K180030
Trade/Device Name: TYRX Absorbable Antibacterial Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 22, 2018
Received: March 23, 2018

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. 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.

Additionally, we would like to inform you that, based on your product being a combination product, your shelf-life protocol cannot be considered approved. Therefore, any additional changes to the shelf-life of the device could warrant a new 510(k) premarket notification. We recommend that you submit a request for a Pre-Submission to discuss any future changes to the device. Your submission should reference this 510(k), identify any changes that you are proposing to make, and indicate your preferred feedback mechanism (i.e., email, meeting or teleconference). For additional information regarding Q-Submissions, please refer to the Guidance for Industry and FDA Staff on Medical Devices: The Pre-Submission Program and Meetings with FDA Staff at:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K180030

Device Name
TYRX Absorbable Antibacterial Envelope

Indications for Use *(Describe)*
The absorbable antibacterial 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 absorbable antibacterial 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. This device is only 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.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared:	April 20, 2018
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 Senior Regulatory Affairs Manager Medtronic Cardiac Rhythm Heart Failure 763.526.8134 wendy.a.saunders@medtronic.com
Submission Type:	Traditional 510(k): Shelf Life Extension and Modified Packaging
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 Devices:	AIGIS$_{RX}$ R, K130943 **rebranded as TYRX™ Absorbable Antibacterial Envelope**

Device Description

TYRX™ Absorbable Antibacterial Envelope (TYRX Envelope) is a sterile prosthesis comprised of two components; an absorbable substrate mesh, and a resorbable 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 knitted filaments of Glycoprene II, a polymer composed of glycolide, caprolactone, and trimethylene carbonate polymer, which are coated with a bioresorbable polyarylate polymer containing the drug substances rifampin and minocycline.

Like its predicate device (originally named, AIGIS$_{RX}$ R), the TRYX 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 absorbable antibacterial 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 absorbable antibacterial 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. This device is intended to be used only 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. TYRX Envelope is identical to its predicate device, cleared under the name AIGIS$_{RX}$ R. The change in packaging and 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

The extended shelf life TYRX Envelopes incorporate a modified packaging configuration (dual chamber foil pouch with desiccant) relative to the predicate device. The modified foil pouch packaging is constructed of similar materials (layered polyethylene and foil) and the foil pouch peel strength requirement is the same as the current packaging. The device is exposed to the same materials as the currently marketed device. The change in packaging provides greater protection from moisture, allowing an extension of the labeled shelf life. The modified packaging has been validated for use and demonstrated to meet the same sterility assurance level as the currently marketed package.

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, in modified foil pouch packaging continue to meet all product requirements through the proposed shelf life. There are no changes to the finished product TYRX Envelope specification as a result of the modifications described in this submission. Other than modified packaging, 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 package verification/validation activities and 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 specification and other than modified packaging, there are no changes to the TYRX Envelope design, materials, mechanism of action, patient contact or intended use. 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 specification, using the same analytical test methodologies, as the currently marketed device. Therefore, the TYRX Envelope device, as modified with extended shelf life and dual pouch with desiccant packaging, 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. Modified packaging has been validated for use and product labeling updated to reflect the extended shelf life.