DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 27, 2015

Medtronic Tyrx, Inc.
Regina Novak
Senior Regulatory Affairs Specialist
1 Deer Park Drive Suite G
Monmouth Junction, New Jersey 08852

Re: K150291
Trade/Device Name: TYRX Neuro Absorbable Antibacterial Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: February 4, 2015
Received: February 6, 2015

Dear Ms. Novak:

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.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150291

Device Name
TYRX Neuro Absorbable Antibacterial Envelope

Indications for Use *(Describe)*
TYRX Neuro Absorbable Antibacterial Envelope is intended to hold a vagus nerve stimulator, a spinal cord neuromodulator, a deep brain stimulator or a sacral nerve stimulator securely in order to create a stable environment when implanted in the body.

TYRX Neuro 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 pulse generator. This device is intended to be used in conjunction with vagus nerve stimulators or deep brain stimulators implanted in the infraclavicular fossa, or in conjunction with spinal cord neuromodulators or sacral nerve stimulators implanted laterally to the body midline and slightly superior to the gluteal region.

TYRX Neuro Absorbable Antiqacterial Envelope is intended for single patient, one-time use only.

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

In accordance with 21 CFR 807.92, Medtronic TYRX, Inc. provides this summary of the safety and effectiveness information available for TYRX™ Neuro Absorbable Antibacterial Envelope, as well as the substantial equivalence decision making process used for the TYRX™ Neuro Absorbable Antibacterial Envelope subject device.

Sponsor/Applicant Name and Address:	Medtronic TYRX, Inc. 1 Deer Park Drive Suite G Monmouth Junction, N.J. 08852
Establishment Registration Number:	3005619263
Sponsor Contact Information:	Regina Novak Senior Regulatory Affairs Specialist Phone: 732-964-1492 Fax: 732-246-8677 Email:regina.novak@medtronic.com Alternate Contact: Susan Olinger, JD Director, Regulatory Affairs Phone: 732-964-1110 Fax: 763-246-8677 Email:susan.olinger@medtronic.com
Date of preparation of 510(k) Summary	February 4, 2015
New Device Trade/Proprietary Name:	TYRX™ Neuro Absorbable Antibacterial Envelope
Device Common Name: Regulatory Classification: PROCODE:	Surgical Mesh Class II FTL
Predicate Device Name and 510(k) Number	TYRX ™ Neuro Absorbable Antibacterial Envelope K142611

Device Description:

TYRX ™ Neuro Absorbable Antibacterial Envelope is a fully absorbable, dual component sterile device designed to hold a vagus nerve stimulator (VNS), a deep brain stimulator (DBS), a spinal cord neuromodulator (SCN) or a sacral nerve stimulator (SNS) securely to create a stable environment when implanted in the body. It is constructed of knitted filaments of a commercially available absorbable polymer, Glycoprene II, comprised of glycolide, caprolactone and trimethylene carbonate polymer, and coated with an absorbable polyarylate polymer mixture containing the antimicrobial agents rifampin and minocycline. Rifampin and minocycline have been shown to reduce infection in an *in vivo* model of bacterial challenge following surgical implantation of an implantable electronic device. This device is to be used in a healthcare facility/hospital by qualified personnel experienced in the procedure of VNS, DBS, SCN, or SNS implantation.

Indications for Use

TYRX ™ Neuro Absorbable Antibacterial Envelope is intended to hold a vagus nerve stimulator, deep brain stimulator, spinal cord neuromodulator, or sacral nerve stimulator securely in order to create a stable environment when implanted in the body.

TYRX ™ Neuro 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 pulse generator. This device is intended to be used in conjunction with vagus nerve stimulators or deep brain stimulators implanted in the infraclavicular fossa or in conjunction with spinal cord neuromodulators or sacral nerve stimulators implanted laterally to the body midline and slightly superior to the gluteal region.

The only difference between the subject and predicate device is that the subject device has an expanded Indication for Use to include use in conjunction with deep brain stimulators and sacral nerve stimulators.

TYRX™ Neuro Absorbable Antibacterial Envelope is intended for single-patient, one-time use only.

Technological Results

The technological characteristics of the TYRX™ Neuro Absorbable Antibacterial Envelope are identical to the predicate. Both devices have the same intended use which is to create a stable environment for the implanted device.

The TYRX™ Neuro Absorbable Antibacterial Envelope is fully absorbable containing the absorbable Glycoprene II substrate mesh and coated with an absorbable polyarylate polymer coating containing the antibiotics rifampin and minocycline in concentrations of 102µg/cm^2 .

There is no difference in the manufacturing processes for the subject device. The difference is only an extension of the Indications for Use to include use in conjunction with Deep Brain Stimulators or Sacral Nerve Stimulators.

Biocompatability Results

TYRX™ Neuro Absorbable Antibacterial Envelope is supplied sterile, biocompatible, and non-pyrogenic. TYRX follows the ISO 11137 standard for sterility.

Biocompatability testing of the predicate device in accordance with ISO 10993 demonstrated the safety of the subject device.

Animal Studies

In vitro studies referenced in the predicate device 510(k), K142611, demonstrated antimicrobial activity against Methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus aureus, Acinetobacter baumannii, Staphylococcus epidermidis*, *Staphylococcus lugdunensis* and *Escherichia coli.*

In vivo efficacy testing, referenced in the predicate device 510(k), K142611, demonstrated effectiveness in reducing infections. The bacteria tested were *Staphylococcus aureus, Acinetobacter baumannii*, *Staphylococcus epidermidis* and *Escherichia coli*, Methicillin-resistant *Staphylococcu aureus* (MRSA), and *Staphylococcus lugdunensis*. It should be noted that the *in vivo* and *in vitro* activity of the TYRX ™ Antibacterial Envelope antimicrobials is variable against non-epidermidis strains of coagulase-negative Staphylococci.

To provide additional evidence on the safety of TYRX Neuro Absorbable Antibacterial Envelope when implanted with neuromodulators, an animal study was conducted to address the question of minocycline diffusion with the TYRX Neuro Antibacterial Envelope (absorbable and non-absorbable) and possible central nervous system (CNS) effects. The purpose of the study was to determine the concentration of minocycline and rifampin in the plasma and cerebrospinal fluid of sheep implanted with a neuromodulator and a TYRX Neuro Antibacterial Envelope (absorbable or non-absorbable), with or without a lead.

The study consisted of four (4) treatment groups: sheep in Group 1 received either a TYRX Neuro Envelope or TYRX Neuro Absorbable envelope with a neuromodulator; sheep in Groups 2 and 3 received either a TYRX Neuro Envelope or TYRX Neuro Absorbable Envelope and neuromodulator and a lead. Sheep in Group 4 were implanted with a single neuromodulator without the TYRX Neuro Envelopes and received oral doses of minocycline and rifampin daily. Each group consisted of 2 sheep and the study duration was for 7 days.

The study demonstrated that the TYRX Neuro Absorbable Antibacterial Envelope was safe in the sheep model as assessed by the absence of adverse clinical signs. There were no quantifiable concentrations of minocycline or rifampin in plasma and cerebrospinal fluid samples collected up to 7 days after implantation of the neuromodulator enclosed in the TYRX Neuro Absorbable Antibacterial Envelope, with or without leads. This study demonstrated that the amount of

minocycline in CSF and plasma, as a result of the TYRX Neuro Absorbable Antibacterial Envelope implantation, are not detectable and do not pose a significant risk for CNS side effects.

CONCLUSION:

In summary, the TYRX Neuro Absorbable Antibacterial Envelope is identical in terms of physical construct to the cleared predicate, TYRX Neuro Absorbable Antibacterial Envelope. The polymer coating containing the antibiotics rifampin and minocycline in concentrations of 102μg/cm^2 applied to the substrate remains unchanged. The device is sterile and non-pyrogenic. The implantation site is the same anatomical location as the currently cleared predicate device, the infraclavicular fossa for spinal cord neuromodulators and laterally to the body midline and slightly superior to the gluteal region for the currently cleared vagus nerve stimulators. The only difference is that the subject device has an expanded Indications for Use to include use in conjunction with Deep Brain Stimulators and Sacral Nerve Stimulators.

Based on the 510(k) summaries and the information provided, we conclude that TYRX ^{TM} Neuro Absorbable Antibacterial Envelope is safe and effective for its intended use, and is substantially equivalent to the predicate device TYRX Neuro Absorbable Antibacterial Envelope (K142611).