



Food and Drug Administration
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November 17, 2015

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

Re: K152678

Trade/Device Name: Tyrx Neuro Antibacterial Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 17, 2015
Received: September 18, 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,

William J. Heetderks -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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(K) Number (if known)

K152678

Device Name

TYRX Neuro Non-Absorbable Antibacterial Envelope

Indications for Use (Describe)

TYRX Neuro Non-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 Non-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 infratemporal 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 Non-Absorbable Antibacterial 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, TYRX, Inc. provides this summary of the safety and effectiveness information available for TYRX™ NeuroNon-Absorbable Antibacterial Envelope, as well as the substantial equivalence decision making process used for the TYRX™ Neuro Antibacterial Envelope subject device.

Sponsor/Applicant Name and Address:

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DBA
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Establishment Registration Number:

3005619263

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Date of preparation of 510(k) Summary

September 17, 2015

New Device Trade/Proprietary Name:

TYRX™ Neuro Non-Absorbable
Antibacterial Envelope

Device Common Name:

Surgical Mesh

Regulatory Classification:
PROCEDURE:

Class II
FTL

Predicate Device Name and 510(k) Number

Primary Predicate
AIGIS_{Rx}[®]N
Antibacterial Envelope
K132699

TYRX[™] Neuro Absorbable
Antibacterial Envelope
K150291

Device Description:

TYRX[™] Neuro Non-Absorbable Antibacterial Envelope is a dual component (absorbable and non-absorbable) 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. The device is available in 2 sizes, Medium (2.5" x 2.7") and Large (2.9" x 3.3"). The device is constructed of knitted filaments of polypropylene (mesh substrate) that are 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 pulse generator. This device is to be used in a healthcare facility/hospital by personnel experienced in the implantation of VNS, DBS, SCN, or SNS.

Indications for Use

TYRX[™] Neuro Non-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 Non-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 and spinal cord neuromodulators or sacral nerve stimulators implanted laterally to the body midline and slightly superior to the gluteal region.

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

Technological Characteristics

The technological characteristics of the TYRX Neuro Non-Absorbable Antibacterial Envelope are identical to the predicate (K132699). Both devices have the same intended use which is to create a stable environment for the implanted neurostimulator.

The only difference between the subject and predicate device (K132699) is that the subject device will have an expanded Indications for Use to include deep brain stimulators and sacral nerve stimulators, the same indications for use as K1250291.

The TYRX™ Neuro Non-Absorbable Antibacterial Envelope is constructed of knitted filaments of polypropylene and coated with an absorbable polyarylate polymer coating containing the antibiotics rifampin and minocycline each in concentrations of $102\mu\text{g}/\text{cm}^2$.

The physical, chemical and mechanical properties of the TYRX Neuro Non-Absorbable Antibacterial Envelope, subject device, are the same as the predicate device (K132699). There is no technological difference between the subject and predicate device, and there are no design changes to the predicate device. The difference is only an expansion of the Indications for Use to include use with Deep Brain Stimulators and/or Sacral Nerve Stimulators, the same as the Indications for Use for K150291.

Biocompatibility Results

Biocompatibility testing in accordance to the current ISO 10993 series was conducted and the results indicate that the device is biocompatible, per the standards.

An *in vivo* functionality study showed that TYRX devices do not alter or interfere with an implantable pulse generator.

Animal Studies

In vitro studies referenced in the predicate devices K132699 and K150291 demonstrated antimicrobial activity against methicillin resistant *Staphylococcus aureus* (MRSA), *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Escherichia coli*, *Acinetobacter baumannii*, *Enterobacter aerogenes*, and *Proteus Mirabilis*.

In vivo efficacy testing referenced in the predicate devices K132699 and K150291, demonstrated effectiveness in reducing infections. The bacteria tested were methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Acinetobacter baumannii*, *Escherichia coli* and *Staphylococcus lugdunensis*. It should be noted that the *in vivo* and *in vitro* activity of the TYRX™ Neuro Non-Absorbable Antibacterial Envelope antimicrobials is variable against non-*epidermidis* and non-*lugdunensis* strains of coagulase-negative Staphylococci.

To provide additional evidence on the safety of TYRX™ Neuro Antibacterial Envelopes when implanted with neuromodulators, a study in sheep 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 (K150291) or non absorbable (K132699), with or without a lead.

The study demonstrated that the TYRX Neuro 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 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 Antibacterial Envelope implantation is not detectable and does not pose a significant risk for CNS side effects.

CONCLUSION:

In summary, the TYRX Neuro Non-Absorbable Antibacterial Envelope is identical in terms of physical construct to the cleared primary predicate, AIGIS Neuro Antibacterial Envelope,(K132699). The polymer coating concentration of the antibiotics rifampin and

minocycline remains unchanged. The device is supplied sterile. The only difference is that the subject device has an expanded Indications for Use to include use with Deep Brain Stimulators and Sacral Nerve Stimulators, which is identical to predicate K150291.

Based on the 510(k) summaries and the information provided, we conclude that TYRX™ Neuro Non-Absorbable Antibacterial Envelope is safe and effective for its intended use, and is substantially equivalent to the primary predicate device (K132699).