



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

December 31, 2014

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

Re: K142611  
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: November 25, 2014  
Received: November 26, 2014

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 (and 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

## Indications for Use Statement

510(k) number (if known): K142611

**Device Name:** TYRX™ Neuro Absorbable Antibacterial Envelope

TYRX™ Neuro Absorbable Antibacterial Envelope is intended to hold a vagus nerve stimulator or spinal cord neuromodulator 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 implanted in the infraclavicular fossa, or spinal cord neuromodulators implanted laterally to the body midline and slightly superior to the gluteal region.

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

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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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	September 15, 2014
New Device Trade/Proprietary Name:	TYRX™ Neuro Absorbable Antibacterial Envelope
Device Common Name:	Surgical Mesh
Regulatory Classification:	Class II
PROCEDURE:	FTL

Predicate Device Name and 510(k) Number

AIGIS<sub>Rx</sub> N Antibacterial Envelope  
(K132699)  
(Primary Predicate)

AIGIS<sub>Rx</sub> Resorbable Antibacterial  
Envelope  
(K130943)

### **Device Description:**

TYRX<sup>™</sup> Neuro Absorbable Antibacterial Envelope is a fully absorbable , dual component sterile device designed to hold a vagus nerve stimulator or spinal cord neuromodulator securely to create a stable environment when implanted in the body. It is constructed of knitted filaments of a commercially available absorbable polymer, Glycocrene 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 personnel experienced in the procedure of vagus nerve or spinal cord neuromodulator implantation.

### **Indications for Use**

TYRX<sup>™</sup> Neuro Absorbable Antibacterial Envelope is intended to hold a vagus nerve stimulator or spinal cord neuromodulator securely in order to create a stable environment when implanted in the body.

TYRX<sup>™</sup> 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 implanted in the infraclavicular fossa, or spinal cord neuromodulators implanted laterally to the body midline and slightly superior to the gluteal region.

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

The Indications for Use statement for TYRX Neuro Absorbable Antibacterial Envelope is identical to the primary predicate. Both devices have the same intended use which is to create a stable environment for a vagus nerve stimulator or spinal cord neuromodulator when implanted.

### **Comparison of Technological Characteristics with the Predicate Device**

TYRX™ Neuro Absorbable Antibacterial Envelope (subject device) is identical in Indication for Use to its predicate, AIGIS N (K132699). Both devices are intended to hold a vagus nerve stimulator or spinal cord neuromodulator securely in order to create a stable environment when implanted in the body. The difference is that TYRX™ Neuro Absorbable Antibacterial Envelope is fully absorbable containing the absorbable Glycoprene II substrate mesh, whereas AIGIS N is partially absorbable; containing the nonabsorbable polypropylene polymer substrate mesh. Both AIGIS N and TYRX Neuro Absorbable Antibacterial Envelope are coated with the identical absorbable polyarylate polymer coating containing the antibiotics rifampin and minocycline in concentrations of 102µg/cm<sup>2</sup>.

TYRX™ Neuro Absorbable Antibacterial Envelope has the same substrate material found in the FDA cleared AIGIS<sub>Rx</sub> R (K130943)(predicate for mesh substrate only). Both devices are fully absorbable. The fully absorbable substrate mesh is constructed of knitted filaments of a commercially available absorbable polymer, Glycoprene II, comprised of glycolide, caprolactone and trimethylene carbonate polymer. There is no difference in the manufacturing processes for the subject device. The difference is that the predicate device (K 132699) substrate mesh is composed of polypropylene and the TYRX™ Neuro Absorbable Antibacterial Envelope (subject device) has Glycoprene II as the substrate mesh.

### **Biocompatibility Results**

TYRX™ Neuro Absorbable Antibacterial Envelope is supplied sterile, biocompatible, and non-pyrogenic. TYRX follows the ISO 11137 standard for sterility. Bench testing demonstrated that the Glycoprene II mesh degrades into its constituent monomers, and there is no chemical or physical interaction between the Glycoprene mesh, the polyarylate coating or the antibiotics.

Biocompatibility testing of the predicate devices in accordance with ISO Standard 10993 demonstrated the biocompatibility and safety of the subject device.

## Animal Studies

In *in vitro* studies, predicates K132699 and K130943 demonstrated antimicrobial activity against *Methicillin Resistant Staphylococcus aureus* (MRSA), *Staphylococcus aureus*, *Acinetobacter baumannii*, *Staphylococcus epidermidis*; K130943 also demonstrated antimicrobial activity against *Staphylococcus lugdunensis* and *Escherichia coli*.

*In vivo* efficacy testing, previously submitted with the primary predicate, K132699, demonstrated effectiveness in reducing infections. The bacteria tested were *Staphylococcus aureus*, *Acinetobacter baumannii*, *Staphylococcus epidermidis* and *Escherichia coli*. *In vivo* efficacy testing, previously submitted with predicate K130943, demonstrated effectiveness in reducing infections with these additional bacteria, methicillin-resistant *Staphylococcus 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.

## CONCLUSION:

In summary, the TYRX Neuro Absorbable Antibacterial Envelope is identical in terms of physical construct to the currently marketed AIGIS N (K132699) except that for the subject device, a bioabsorbable, multi filament surgical mesh (Glycophrene II) will replace the monofilament polypropylene surgical mesh substrate in the non absorbable predicate device. The polymer coating containing the antibiotics rifampin and minocycline in concentrations of  $102\mu\text{g}/\text{cm}^2$  applied to the substrate will remain unchanged. The device is sterile and non-pyrogenic.

Based on the 510(k) summaries and the information provided, we conclude that TYRX™ Neuro Absorbable Antibacterial Envelope is safe and effective for its intended use, and is substantially equivalent to the predicate device AIGIS N (K132699) from the perspective of Indication for Use and substantially equivalent to the predicate device (AIGIS R, K130943) from the perspective of technological characteristics and shelf life (1 month).