K132699

510(k) Summary

NOV 26 2013

In accordance with 21 CFR 807.92, TYRX Inc. provides this summary of the safety and effectiveness information available for AIGISRx® N, as well as the substantial equivalence decision making process used for the AIGISRx® N subject device.

Sponsor/Applicant Name and Address:

TYRX Inc.
1 Deer Park Drive Suite G
Monmouth Junction, N.J. 08852

Establishment Registration Number:

3005619263

Sponsor Contact Information:

Regina Novak
Manager, Regulatory Affairs
Phone: 732-964-1492
Fax: 732-964-1490
Email: rnovak@tyrx.com

Alternate Contact:
Susan Olinger, JD
Vice President, Regulatory Affairs
Phone: 732-964-1110
Fax: 732-964-1490
Email: solinger@tyrx.com

Date of Preparation of 510(k) Summary:

August 28, 2013

New Device Trade/Proprietary Name:

AIGISRx® N

Device Common/Classification Name:

Surgical Mesh, Class II
PROCODE: FTL

Predicate Device Name and 510(k) Number: AIGIS$_{Rx}$® N (K131007)

Device Description:

AIGIS$_{Rx}$ N is a dual component (resorbable and non-resorbable) sterile prosthesis 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 polypropylene that are coated with a bioresorbable polyarylate polymer 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.

Device Intended Use:

AIGIS$_{Rx}$® N 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. AIGIS$_{Rx}$® N 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.

The only difference between the subject and predicate devices is that the subject device has an expanded indication for use to include spinal cord neuromodulators (SCNM).

Technological Characteristics:

The physical, chemical and mechanical properties of the AIGIS N subject device, such as mesh knit characteristics, suture retention strength, tear strength and burst strength are the same as the AIGIS$_{Rx}$® N predicate device. There is no change to the design, materials of construction, or manufacturing processes for the subject device. There are no technological differences between the subject and predicate devices, and there are no design changes to the predicate device.

Performance Data:

AIGISRx N is designed to be a biocompatible, sterile device 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 AIGISRx N subject device is identical to the AIGISRx N predicate device. Information on the cleared predicate device, K131007, is included by reference in this 510(k).

AIGISRx N is sterile, biocompatible, and non-pyrogenic. Sterility conforms to ISO 11137, and bench testing shows that gamma sterilization has no detrimental effect on the chemical structure or thermal properties of the polypropylene substrate mesh. Standard ISO 10993 testing demonstrated the biocompatibility and safety of the device. An *in vivo* functionality study showed that AIGIS devices do not alter or interfere with an implantable pulse generator. The AIGISRx device (K063091) was the device used in the aforementioned studies and it was the predicate for AIGIS N (K131007), which was cleared on July 10, 2013. The AIGISRx N subject device is identical to the AIGISRx N predicate device (K131007), there is no change to the design, materials of construction or manufacturing processes for the subject device. There are no technological differences or design changes. AIGIS N (K131007) is the predicate for our subject device, therefore, we believe that these studies are directly applicable to this new 510K. Information on the cleared predicate device, K131007, is included by reference in this 510(k).

To provide additional evidence on the safety of AIGIS N when implanted with SCNM, a study was conducted to address the question of minocycline diffusion from the AIGIS N device and possible CNS effects. The purpose of the study was to determine concentrations of minocycline and rifampin in the plasma and cerebrospinal fluid (CSF) of sheep implanted with a SCNM and an AIGISRx® antibacterial envelope, with or without a spinal lead.

This study consisted of four (4) treatment groups; sheep in Group 1 received AIGIS or AIGIS R envelope with a SCNM; sheep in Groups 2 & 3 received AIGIS or AIGIS R and SCNM and a lead. Sheep in Group 4 were implanted with a single SCNM without the AIGIS device and received oral doses of minocycline and rifampin daily. Each group consisted of 2 sheep and the study duration was 7 days.

The study demonstrated that the AIGISRx N 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 CSF samples collected up to 7 days after implantation of the SCNM enclosed in the AIGISRxN Antibacterial envelope, with or without leads. This study demonstrated that the amount of minocycline in CSF

and plasma, as a result of AIGIS$_{Rx}$ N implantation, are not detectable and do not pose a significant risk for CNS side effects.

Conclusions:

Both the AIGIS$_{Rx}$ N predicate and the AIGIS$_{Rx}$ N subject devices are safe and effective for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 26, 2013

TYRX, Inc.
c/o Regina Novak
Manager, Regulatory Affairs
1 Deer Park Drive, Suite G
Monmouth Junction, NJ 08852

Re: K132699
Trade/Device Name: AIGISRx N
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 4, 2013
Received: September 5, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132699

Device Name: AIGISRx N Antibacterial Envelope

Indications For Use:

AIGISRx N 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. AIGISRx N 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.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S