510(k) Summary

MAY 2 0 2013

In accordance with the regulations, TYRX provides this summary of the safety and effectiveness information for the AIGISRX®R (AIGIS R) device. This summary includes the substantial equivalence decision algorithm used for AIGIS R.

Sponsor/Applicant Name and Address:

TYRX, Inc.
One Deer Park Drive
Monmouth Junction, NJ 08852

Establishment Registration Number:

3005619263

Sponsor Contact Information:

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Date of Preparation of 510(k) Summary:

March 29, 2013

New Device Trade/Proprietary Name:

AIGISRx®R

Device Common Name:

Surgical Mesh, Class II

Classification Name:

Procode: FTL

Predicate Devices Names and 510(k) Numbers:

AIGISRX® K063091

Device Description:

AIGISRx® R (AIGIS R) is a fully resorbable, dual component sterile prosthesis designed to hold and stabilize a cardiovascular electronic implantable device (CIED), such as a pacemaker or an implantable cardioverter- defibrillator (ICD), when the electronic device is implanted in the body. AIGIS R is constructed of knitted filaments of a commercially available resorbable polymer, Glycoprene II, comprised of glycolide, caprolactone, trimethylene carbonate polymer, and coated with a bioresorbable polyarylate polymer mixture containing the antimicrobial agents rifampin and minocycline in concentrations of 102 $\mu g/cm.^2$

Device Intended Use:

AIGIS R is intended to hold a pacemaker pulse generator or defibrillator securely in order to create a stable environment when implanted in the body. AIGIS R 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 of defibrillator. This device is intended to be used only in conjunction with pacemakers or defibrillators.

AIGIS R is intended for single-patient, one-time use only.

Performance Data:

AIGIS R 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. AIGIS R is identical to its predicate device, the FDA cleared AIGISRX® (AIGIS) antibacterial envelope, [information is incorporated by reference into this 510(k)], except that the AIGIS R device's surgical mesh substrate is the bioresorbable mesh Glycoprene II, and the AIGIS substrate is a nonresorbable polypropylene polymer mesh. The change from a polypropylene substrate mesh to the Glycoprene mesh renders the AIGIS R device completely resorbable, while with the AIGIS device, only the polyarylate polymer coating is resorbable.
The drug content label claim for AIGIS is up to 11 mg each of rifampin and minocycline (PM size) and up to 16 mg each of rifampin and minocycline (ICD size). The label claim for AIGIS R is:

PM size (Medium):
Rifampin – 8.0 mg
Minocycline – 5.1 mg
ICD size (Large):
Rifampin – 11.9mg
Minocycline – 7.6 mg

All forms of the AIGISRx family of devices are supplied sterile, biocompatible, and non-pyrogenic. TYRX follows the ISO 11137 standard for sterility. Furthermore, bench testing of the AIGIS family of devices demonstrated that gamma sterilization has no effect on the chemical structure or thermal properties of Glycoprene II mesh. Bench testing also demonstrated that AIGIS R degrades into its constituent monomers, and that there is no chemical or physical interaction between the Glycoprene mesh, the polyarylate coating, or the antibiotics. Testing, according to ISO Standard 10993, demonstrated the biocompatibility and safety of the device. *In vivo* studies demonstrated that the AIGIS R device does not interfere with the functioning of the implantable cardiovascular electronic device. Moreover, anti-microbial effectiveness (AME) studies, both *in vivo* and *in vitro*, demonstrated that the AME of AIGIS R is equivalent to AIGIS.

Conclusions:

AIGIS R is safe and effective for its intended use, and is substantially equivalent to the predicate device, AIGIS.

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

May 20, 2013

Tyrx, Inc.
c/o Ms. Susan Olinger
1 Deer Park Drive, Suite G
Monmouth Junction, NJ 08854

Re: K130943
Trade/Device Name: AIGIS$_{RX}$ R Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 29, 2013
Received: April 04, 2013

Dear Ms. Olinger:

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,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) number (if known): K130943

Indication for Use:

AIGISRx® R is intended to hold a pacemaker pulse generator or defibrillator securely in order to create a stable environment when implanted in the body. **AIGIS$_{Rx}$® R** contains the antimicrobial agents rifampin and minocycline which have been shown to reduce infection in *in vivo* models 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.

AIGISRx® R is intended for single patient, one-time use only.

Prescription use_____X_____ and/or Over the counter use_____
(21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

PLEASE DO NOT WRITE ABOVE THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2013.05.20
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