SECTION 5. 510(K) SUMMARY

JAN 16 2008

510(K) SUMMARY (AS REQUIRED BY 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)3A of the Safe Medical Devices Act of 1990, TyRx Pharma, Inc. is providing a summary of the safety and effectiveness information available for TyRx AIGIS$_{RX}$™ Anti-bacterial Envelope, as well as the substantial equivalence decision making process used for TyRx AIGIS$_{RX}$™ Anti-bacterial Envelope.

Sponsor/Applicant Name and Address:
TyRx Pharma, Inc.
1 Deer Park Drive, Suite G
Monmouth Junction, NJ 08852

Sponsor Contact Information:
Mark Citron
Vice President, Clinical and Regulatory Affairs
Phone: 732-246-8676
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Date of Preparaton of 510(k) Summary:
January 14, 2008

New Device Trade/Proprietary Name:
AIGIS$_{RX}$™ Anti-bacterial Envelope

Device Common/Classification Name:
Bag, Polymeric Mesh, Pacemaker

Predicate Devices Name and 510(k) Numbers:

- Bard Parsonnet Pacemaker Pouch (Listing Number 2212754)
- Pivit AB (TyRx Antimicrobial Mesh) (K053656)
- OrthoGuard AB Antimicrobial Sleeve (K012198)

Device Description
AIGIS$_{RX}$ is a dual component (resorbable and non-resorbable), sterile prosthesis designed to hold a pacemaker pulse generator or defibrillator to create a stable environment when implanted in the body. AIGIS$_{RX}$ is constructed of knitted filaments of polypropylene that are coated with a bioresorbable polyarylate polymer. AIGIS$_{RX}$ bioresorbable polymer coating contains the antimicrobial agents, rifampin and minocycline in concentrations of 86 $\mu g/cm^2$.

Device Intended Use:

AIGIS$_{RX}$ is intended to securely hold a pacemaker pulse generator or defibrillator in order to create a stable environment when implanted in the body. AIGIS$_{RX}$ 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 the generator or defibrillator. This device is only intended to be used in conjunction with pacemakers and implantable defibrillators.

Performance Data:
AIGIS$_{RX}$ is constructed of knitted filaments of polypropylene that are coated with a bioresorbable polyarylate polymer. The purpose of the resorbable coating is to act as a carrier for the antimicrobial agents. Once placed, the polymer resorbs in approximately 140 days leaving a light-weight permanent mesh incorporated into the tissue.

AIGIS$_{RX}$ releases the antimicrobial agents, rifampin and minocycline for a minimum of 7 days to reduce the risk of infection of the implanted pulse generator following surgery. In *in vitro* studies, AIGIS$_{RX}$ demonstrated antimicrobial activity against Methicillin Resistant *Staphylococcus aureus* (MRSA), *Staphylococcus aureus, Staphylococcus epidermidis, Acinetobacter baumanii, Enterobacter aerogenes* and *Proteus mirabilis.*

AIGIS$_{RX}$™ also demonstrated *in vivo* effectiveness in reducing infections in a series of studies in which a pulse generator canister placed into a AIGIS$_{RX}$™ pouch and generator canister alone (Control) were implanted into appropriate models of infectivity (dogs or rabbits). Both AIGIS$_{RX}$™ and the controls were inoculated and observed for a minimum of 7 days to validate the presence of infection in the animals. The bacteria tested included *Staph aureus, Staph epidermidis, Acinetobacter baumanii, and E coli* which represent a majority of the infections reported in pacemaker-related endocarditis. It should be noted that the *in vitro* and *in vivo* activity of the AIGIS$_{Rx}$ antimicrobials is variable against non-epidermidis strains of coagulase-negative staphylococci

Conclusions:
Based on the 510(k) summaries (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Devices under the Federal Food Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2008

TyRx Pharma, Inc.
c/o Mr. Mark Citron
Vice President
1 Deer Park Drive
Monmouth Junction, NJ 08852

Re: K063091
AIGIS$_{RX}$ Anti-Bacterial Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: January 3, 2008
Received: January 4, 2008

Dear Mr. Citron:

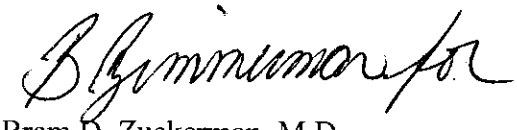
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063091

Device Name: *AIGIS$_{RX}$™* Anti-Bacterial Envelope

INDICATIONS/CONTRAINDICATIONS:

INDICATIONS FOR USE

AIGIS$_{RX}$ is intended to securely hold a pacemaker pulse generator or defibrillator in order to create a stable environment when implanted in the body. **AIGIS$_{RX}$** 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 the generator or defibrillator. This device is only intended to be used in conjunction with pacemakers and implantable defibrillators.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063091

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)