Revised 510(K) Summary

JUL 14 2006

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 PivitAB™, as well as the substantial equivalence decision making process used for PivitAB™.

Sponsor/Applicant Name and Address:
TyRx Pharma, Inc.
1 Deer Park Drive, Suite G
Monmouth Junction, NJ 08852
Registration Number: 3005619263

Sponsor Contact Information:
Mason Diamond, DDS
Vice President, Clinical and Regulatory Affairs
Phone: 732-246-8676
Fax: 732-246-8677
E-mail: mason@tyrxpharma.com

Date of Preparaton of 510(k) Summary:
December 29, 2005

New Device Trade/Proprietary Name:
PivitAB™

Device Common/Classification Name:
Polymeric Surgical Mesh

Predicate Devices Name and 510(k) Numbers:
TyRx Surgical Mesh (K052864)
AMS InteMesh™ Silicone-Coated Sling and Surgical Mesh with InibiZone ™ (K042592)
Spectrum® Central Venous Catheter with or without Hydrophilic Coating (K000343)
GORE-TEX® DualMesh® PLUS Biomaterial (1 mm and 2 mm) (K000185)

Device Description:
PivitAB™ is dual component (resorbable and non-resorbable), sterile prosthesis designed for the reconstruction of soft tissue deficiencies. PivitAB™ is constructed of a non-resorbable mesh comprised of knitted filaments of polypropylene and a bioresorbable polyarylate coating on the mesh containing the antimicrobial agents, rifampin and minocycline. The purpose of the resorbable coating is to provide additional stiffness to the mesh in order to facilitate interoperative handling during placement and act a carrier for the antimicrobial agents. Once placed, the polymer resorbs in approximately 90 days leaving a lighter permanent mesh incorporated into the tissue. In addition, animal testing demonstrated that PivitAB™ would achieve satisfactory tissue ingrowth compared to

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commercial surgical mesh.

Intended Use:
PivitAB™ is intended for the repair of hernias and other abdominal fascial deficiencies requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. The resorbable polymer coating on the mesh contains the antimicrobial agents, rifampin and minocycline to help provide protection from microbial colonization of the device during surgical implantation. Examples of applications where PivitAB™ may be used include, but are not limited to: inguinal, femoral, umbilical, abdominal, incisional and intramuscular hernias and muscle flap reinforcement.

Performance Data:
Non-clinical laboratory testing was performed in accordance with the FDA guidance document "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" demonstrating that the device is comparable to standard surgical mesh devices that are indicated for hernia repair and other abdominal fascial or muscular deficiencies requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. The PivitAB™ and the polyarylate polymer have been demonstrated to be biocompatible. In addition, animal testing demonstrated that PivitAB™ will achieve satisfactory tissue ingrowth compared to control as evidenced by histopathology. PivitAB™ has demonstrated effectiveness in an *in vivo* experiment in which PivitAB™ and a non-antimicrobial coated Control (PROLENE, Ethicon, Sommerville, NJ) were inoculated with 10^5 CFUs of *S aureus* and implanted into rabbits. Result demonstrated that there were significantly fewer colonized implants with PivitAB (13%) than with the PROLENE Mesh control (43%).

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

JUL 14 2006

TyRx Pharma, Inc.
% Mason W. Diamond, D.D.S.
Vice President, Clinical and Regulatory
Affairs
1 Deer Park Drive, Suite G
Monmouth Junction, New Jersey 08852

Re: K053656
Trade/Device Name: PivitAB™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: May 15, 2006
Received: May 16, 2006

Dear Dr. Diamond:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment 2: Revised Indication For Use Statement

Indications for Use

510(k) Number (if known): K053656

Device Name: PivitAB™

Indications for Use:

Is intended for the repair of hernias and other abdominal fascial deficiencies requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. The resorbable polymer coating on the mesh contains the antimicrobial agents, rifampin and minocycline to help provide protection from microbial colonization of the device during surgical implantation. Examples of applications where PivitAB™ may be used include, but are not limited to: inguinal, femoral, umbilical, abdominal, incisional and intramuscular hernias and muscle flap reinforcement.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucher

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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