K093524
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## 510(K) Summary

MAR 2 3 2010

**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 Inc. is providing a summary of the safety and effectiveness information available for PIVIT A/B ST as well as the information used in the substantial equivalence decision making process for PIVIT A/B ST.

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

Sponsor Contact Information:
Mark Citron
Vice President Regulatory Affairs and Quality Systems
Phone: 732-246-8676
Fax: 732-246-8677
E-mail: mark@tyrx.com

Date of preparation of 510(k) summary:
March 24, 2010

New Device Trade/Proprietary Name:
PIVIT A/B ST

Device Common/Classification Name:
Polymeric Surgical Mesh

Predicate Devices Name and 510(k) Numbers:

| | |
|---|---|
| PIVIT A/B | (K053656) |
| Strattice | (K070560) |
| HydroCoat Mesh | (K090271) |

Device Description:
PIVIT A/B ST is identical to the PIVIT A/B device cleared via K053656. This filing is meant to provide for a line extension to the PIVIT A/B device and provide for uses consistent with other surgical mesh devices. This summary is repeated from the original PIVIT A/B clearance as reference.

> *PIVIT A/B ST is dual component (resorbable and non-resorbable), sterile prosthesis designed for the reconstruction of soft tissue deficiencies. PIVIT A/B ST is constructed of a nonresorbable 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 as a carrier for antimicrobial agents. Once placed, the polymer resorbs in approximately 90 days leaving a lighter permanent mesh incorporated into the tissue.*

Intended Use:
PIVIT A/B ST is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

PIVIT A/B™ ST is intended for single patient one-time use only.

Performance Data :
Performance data on the enclosed devices are provided by reference to the previously cleared PIVIT A/B device per K053656.

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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 3 2010

TYRX Pharma, Inc.
% Mr. Mark Citron
VP, Regulatory Affairs and Quality Systems
1 Deer Park Drive, Suite G
Monmouth Junction, New Jersey 08852

Re: K093524
Trade/Device Name: PIVIT A/B™ ST
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 16, 2010
Received: March 17, 2010

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEP DEP

Enclosure

## Indication For Use Statement

**Indications for Use**

510(k) Number ( If known): K093524

Device Name: PIVIT A/B ST

Indications for Use:

PIVIT A/B ST is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. 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.

PIVIT A/B™ ST 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 BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

David Krause for MKM

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K093524