DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 8, 2016

Tissue Regenix Group, PLC
Mr. Mike Izon
Head of Quality, Regulatory & Clinical Affairs
The BioCentre, Innovation Way, Heslington
York, Yorkshire YO10 5NY UK

Re: K152206
Trade/Device Name: SurgiPure XD Reconstructive Tissue Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: January 28, 2016
Received: February 1, 2016

Dear Mr. Izon:

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 Parts 801 and 809); 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TRX Wound Care Limited

PRIVATE AND CONFIDENTIAL

SECTION 4 – INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K152206

Device Name: SurgiPure® XD Reconstructive Tissue Matrix

Indications For Use:

SurgiPure® XD Reconstructive Tissue Matrix 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 membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or buttressing material to obtain the desired surgical outcome.

SurgiPure® XD Reconstructive Tissue Matrixis intended for single patient use only.

Prescription Use x AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

TRX Wound Care Limited

510(k) Summary

TRX Woundcare Ltd.

Submitter's Name and Address:

TRx Woundcare Ltd
Astley Way
Swillington
Leeds
LS26 8XT

Contact Person: Mike Izon
Telephone: +44 03304303061

Date Prepared: 8th March 2016

Common or Usual Name: SurgiPure™ XD Reconstructive Tissue Matrix
Classification Name: Mesh, Surgical
Regulation Number: 878.3300
Device Product Code: FTM

Predicate Device: LTM Surgical Mesh, LifeCell Corporation, K070560

Intended Use/Indications for Use:
SurgiPure™ XD Reconstructive Tissue Matrix 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 membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or buttressing material to obtain the desired surgical outcome. The device is intended for single use (single patient one-time use) only.

Technological Characteristics:
SurgiPure™ XD Reconstructive Tissue Matrix is a surgical mesh made from porcine dermis which then undergoes a decellularisation process. The collagen matrix is subsequently packed into a double pouch and then sterilised by irradiation. SurgiPure™ XD acts as a surgical mesh for soft tissue repair to provide a scaffold to the patient to allow cellular infiltration, neovascularisation and collagen deposition.

Performance Data:
SurgiPure™ XD Reconstructive Tissue Matrix has undergone extensive biocompatibility testing, animal testing, viral inactivation testing and biomechanical testing. The data indicates that the device is biocompatible and that the manufacturing process is capable of inactivating any viral components that may come from the starting material. Cellular material and residual DNA is removed from the device whilst preserving the quality of the collagen structure. Bench testing data demonstrates that SurgiPure™ XD Reconstructive Tissue Matrix will meet the established specifications necessary for consistent performance in accordance with its intended use.

Substantial Equivalence:
SurgiPure™ XD Reconstructive Tissue Matrix is substantially equivalent to the legally marketed predicate, LTM Surgical Mesh – K070560. SurgiPure™ XD Reconstructive Tissue Matrix has the same intended uses and the same or similar indications, technological characteristics and principles of operation as the predicate device. Performance data demonstrates that SurgiPure™ XD Reconstructive Tissue Matrix functions equivalently to the predicate device. Thus, SurgiPure™ XD Reconstructive Tissue Matrix is substantially equivalent.