K091142

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RTI BIOLOGICS

ADVANCING SCIENCE, SAFETY & INNOVATION

AUG 31 2009

# Attachment 6: 510(K) Summary

Submitted by: Lisa Simpson
RTI Biologics, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4326
Fax: 386-418-1627

Proprietary Names: TUTOMESH®, TUTOPATCH®

Common Name: Surgical Mesh

Product Code: FTM, General & Plastic Surgery Panel

Code Section: 21 CFR 878.3300

Substantial Equivalence:
The proposed devices are substantially equivalent to predicate devices in materials, design, function, intended use and fundamental scientific technology.

Description:
These are bovine pericardium surgical mesh devices processed with the Tutoplast® solvent dehydration process followed by gamma irradiation. These devices consist of collagenous connective tissue with three-dimensional intertwined fibers. Therefore, they have multidirectional mechanical strength and can be fixed regardless of the direction of the graft. Collagenous connective tissue with multidirectional fibers retain the mechanical strength and elasticity of the native tissue, while providing the basic structure to support replacement by new endogenous tissue.

Intended Use:
This device is intended for implantation to repair, reinforce and/or supplement soft tissue.

This device is indicated for use in general and plastic surgery applications. This device is intended for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include but are not limited to: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including but not limited to diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).

Summary of Technological Characteristics:
The proposed device has materials, design and function equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 9 2009

RTI Biologics, Inc.
% Mr. Travis Arola
Regulatory Affairs Manager
11621 Research Circle, P.O. Box 2650
Alachua, Florida 32616

Re: K091142
Trade/Device Name: TUTOPATCH®, and TUTOMESH®
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: August 31, 2009
Received: August 31, 2009

Dear Ms. Simpson:

This letter corrects our substantially equivalent letter of August 31, 2009.

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 (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 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,

Barbara Bucheme for

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

K091142

# Attachment 3: Indications for Use

**510(k) Number (if known):** _____

**Device Names:** TUTOPATCH®
TUTOMESH®

**Indications for Use:**

This device is intended for implantation to repair, reinforce and/or supplement soft tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091142