Attachment 1:

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
In Accordance with the
Safe Medical Device Act of 1990

Tutopatch™ bovine pericardium

1) Submitted by:

RTI Biologics, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4347
Fax: 386-418-1627

Contact person:

Travis Arola, MS, RAC, CTBS
Regulatory Affairs Manager
Telephone: (386) 418-8888
Facsimile: (386) 418-1627
E-mail: tarola@rtix.com

2) Original Date Prepared: August 25, 2000
Date Updated: October 24, 2012

3) Name of Medical Device:
Proprietary Name: Tutopatch™ bovine pericardium
Classification Name: Mesh, Surgical

4) Device Classification:

The Center for Devices and Radiological Health has classified bovine pericardium used for general and plastic surgery indications (Mesh, Surgical, Polymeric) as a Class II device pursuant to 21 CFR §878.3300.

Device:	Mesh, Surgical
Medical Specialty:	General and Plastic Surgery
Product Code:	FTM
Class:	2
510(k) Exempt?	No
Regulation Number:	21 CFR §878.3300

5) Device Description:

Tutopatch bovine pericardium is a Tutoplast® Processed, solvent-dehydrated gamma irradiated preserved bovine pericardium surgical mesh. *Tutopatch* bovine pericardium consists of collagenous connective tissue with three-dimensional intertwined fibers. Therefore, it has a multidirectional mechanical strength and can be fixed regardless of the direction of the graft. Collagenous connective tissue with multidirectional fibers retains the mechanical strength and elasticity of the native tissue, while providing the basic formulative structure to support replacement by new endogenous tissue. *Tutopatch* bovine pericardium is supplied in sterile double-packaged peelable pouches and comes in a variety of sizes.

6) Indication for Use:

Tutopatch bovine pericardium is intended for the reinforcement of tissue during general and plastic surgery repair. The labeling reveals that the applicant and all predicate devices have the same intended use as a general and plastic surgery surgical mesh.

7) Technological Characteristics and Substantial Equivalence

Tutopatch bovine pericardium is a Tutoplast® Processed, solvent dehydrated, gamma-irradiated preserved bovine pericardium surgical mesh. All tissues are recovered from cattle free of BSE. The processing of *Tutopatch* bovine pericardium consists of a strict, quality controlled procedure, which involves thorough cleaning, processing, dehydration and preservation. The process leaves no deleterious residue and minimizes antigenic potential.

The Tutoplast® Process begins with thorough screening of the raw tissue such as the bovine pericardium. Tissues meeting the screening criteria are then cleaned with saline solutions of various concentrations, resulting in the osmotic destruction of cells so that the source tissue is reduced to its fiber and mineral components.

After processing with inorganic agents such as hydrogen peroxide and 1N sodium hydroxide, the tissue is preserved by the extraction of water using organic solvents, e.g., acetone. The dense collagenous fiber structure of the tissue is retained during this method of preservation. Collagenous connective tissue with three dimensionally intertwined fibers retains the multidirectional and mechanical strength of native tissue, while providing the basic formative structure to support replacement by new endogenous tissue.

After preservation, the tissue is cut into standardized sizes and packaged in transparent, double peel pouches. The finished products are terminally sterilized by gamma-irradiation. The gamma-irradiated material exhibits excellent tensile strength, burst strength, reapproximates well around suture holes, resisting leakage of fluids. It has a wall thickness similar to that of native pericardium and is flexible, making it convenient to implant. RTI Biologics, Inc. believes that product subjected to the Tutoplast® Process posed no additional questions of safety and effectiveness.

8) Statement of Substantial Equivalence:

Tutopatch bovine pericardium is substantially equivalent in function and intended use to the following devices:
a) Peri-Guard® Pericardium 510(k) K983162
b) Supple Peri-Guard® Pericardium 510(k) K983162
c) Peri-Strips® Staple Line Reinforcement - Sleeve Configuration 510(k) K983162
d) Peri-Strips® Staple Line Reinforcement - Strip Configuration 510(k) K983162
e) Peri-Strips Dry™ Staple Line Reinforcement 510(k) K983162

9) Performance Data:

Tutopatch bovine pericardium has been evaluated by a number of tests for safety, biocompatibility, toxicity, pyrogenicity, sterility and mechanical strength. In all instances, *Tutopatch* bovine pericardium functioned as intended and all test results and characteristics observed were as expected. Summaries and reports of all data are contained in the Premarket Notification submission.

10) Conclusions:

The data collected demonstrate that the device has the necessary structural, biocompatibility, and biomechanical characteristics to function safely and effectively as a surgical mesh.

THIS SPACE IS LEFT BLANK INTENTIONALLY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Tutogen Medical U.S., Inc.
% Mr. P.J. Pardo, MS, MT (ASCP)
Director of Quality Assurance
13709 Progress Boulevard, Box 19
Alachua, Florida 32615

July 1, 2013

Re: K991296
Trade/Device Name: TUTOPATCH®
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXH, PAJ, DXZ
Dated: August 25, 2000
Received: September 6, 2000

Dear Mr. Pardo:

This letter corrects our substantially equivalent letter of October 6, 2000.

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 contact 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. 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

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2: Indications for Use

510(k) Number (if known): K991296

Device Names: Tutopatch™ bovine pericardium

Indications for Use:

Tutopatch bovine pericardium is intended for use to reinforce soft tissue where weakness exists in general and plastic surgery applications and is indicated for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: gastric banding, muscle flap reinforcement, repair of rectal prolapse using an abdominal approach (excluding rectocele), reconstruction of the pelvic floor using an abdominal approach (excluding transvaginal repair of pelvic organ prolapse), and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, ventral, scrotal, and umbilical).

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)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K991296