OCT - 6 2000 K991296

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

## TUTOPATCH®

### 1) Submitted by:

Tutogen Medical, Inc.
13709 Progress Blvd., Box 19
Alachua, FL 32615-9537

**Contact Person:**

PJ Pardo, MS, MT(ASCP)
Director Quality Assurance
Telephone: (904) 462-2178
Facsimile: (904) 462-7901
e-mail: pjpardo@mindspring.com

### 2) Date Prepared: August 25, 2000

### 3) Name of Medical Device:

**Proprietary Name:** TUTOPATCH®

**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.

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|---|---|
| **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® is a Tutoplast® processed, solvent-dehydrated gamma irradiated preserved bovine pericardium surgical mesh. TUTOPATCH® implant 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® is supplied in sterile double-packaged peelable pouches and comes in a variety of sizes.

## 6) Indication for Use:

TUTOPATCH® 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® is a Tutoplast® processed, solvent dehydrated, gamma-irradiated preserved bovine pericardium surgical mesh. All tissues are recovered from U.S. cattle free of BSE and inspected / cleared by the United States Department of Agriculture. No pooling of tissues at any phase of the collection or processing is permitted. The processing of TUTOPATCH® 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. Tutogen Medical, Inc., believes that product subjected to the Tutoplast® process posed no additional questions of safety and effectiveness.

## 8) Statement of Substantial Equivalence:

TUTOPATCH® 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® has been evaluated by a number of tests for safety, biocompatibility, toxicity, pyrogenicity, sterility and mechanical strength. In all instances, TUTOPATCH® 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

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

Re: K991296
Trade Name: TUTOPATCH®
Regulatory Class: II
Product Code: FTM
Dated: August 25, 2000
Received: September 6, 2000

Dear Mr. Pardo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Mark N Melkerson

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: Tutogen Medical, Inc.

510(k) Number (if known): K991296

Device Name: TUTOPATCH®

Indications For Use:

TUTOPATCH® is indicated for use in general and plastic surgery applications. TUTOPATCH® is intended for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991296

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