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ADVANCING SCIENCE, SAFETY & INNOVATION

510(K) Summary

K073097

Date: April 17, 2008

Submitted by: Lisa Simpson
RTI Biologics, Inc.
11621 Research Circle
Alachua, FL 32615
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MAY 12 2008

Proprietary Names: TutoDent® Dental Membrane
CopiOs™ Pericardium Membrane

Common Name: Barrier, Animal Source, Intraoral

Classification: Unclassified

Code Section: None

Substantial Equivalence:
The TutoDent® Dental Membrane and CopiOs™ Pericardium Membrane are substantially equivalent to the TutoPatch membrane with respect to materials. The TutoDent® Dental Membrane and CopiOs™ Pericardium Membrane are substantially equivalent to the Collagen Dental Membrane, Bio-Gide Resorbable Membrane and BioMend Extend predicate devices with respect to design and function.

Description:
The TutoDent® Dental Membrane and CopiOs™ Pericardium Membrane are manufactured from bovine pericardium processed with the Tutoplast® process. These membranes are available in sizes ranging from 15 x 20mm to 30 x 40mm.

Intended Use:
This membrane is intended for use in oral surgical procedures as a resorbable material for augmentation around implants placed in immediate extraction sockets, augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

Summary of Technological Characteristics:
The TutoDent® Dental Membrane, CopiOs™ Pericardium Membrane, Collagen Dental Membrane, Bio-Gide Resorbable Membrane and BioMend Extend have substantially equivalent design and function. The TutoDent® Dental Membrane, CopiOs™ Pericardium Membrane and TutoPatch® membrane are composed of the same materials processed in the same manner.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2008

Ms. Lisa Simpson
Director, Regulatory Affairs
RTI Biologics, Incorporated
P.O. Box 2650
11621 Research Circle
Alachua, Florida 32616-2650

Re: K073097
Trade/Device Name: TutoDent® Dental Membrane
CopiOs™ Pericardium Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Graft Material
Regulatory Class: II
Product Code: NPL
Dated: April 17, 2008
Received: April 18, 2008

Dear Ms. Simpson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): K073097

Device Name: TutoDent® Dental Membrane
CopiOs™ Pericardium Membrane

Indications For Use:

This membrane is intended for use in oral surgical procedures as a resorbable material for augmentation around implants placed in immediate extraction sockets, augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

Prescription Use ✓ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073097