K021835

OCT 17 2002

Summary of Safety and Effectiveness
(As required by 21 CFR 807.92)

Device Name: GlucaMesh and or Glucatex (Polypropylene/Polyester) Mesh.

Predicate Device Name: Prolene Soft (Polypropylene), Mersilene (Polyester) and Biomesh (polypropylene) mesh.

Device Description GlucaMesh/Glucatex mesh is constructed of polypropylene or polyester which is identical in composition to that used in Prolene Soft Mesh, Mersilene or Biomesh. The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth.

Intended Use This mesh is intended for the use as a prosthesis in general surgery for surgical treatment of abdominal wall reinforcement, hernia repairs, eventrations, rectal and genitourinary prolapse.

Indications Statement This mesh is used for the repair of abdominal wall reinforcements, hernia repairs, eventrations, rectal or genitourinary prolapses.

Technological Characteristics For technical characteristics, the values established for GlucaMesh and Glucatex are similar to those established by Prolene, Mersilene and Biomesh which were constructed of polypropylene and polyester.

Performance Data Sufficient bench testing was conducted in accordance with the FDA guidance document "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."

Conclusions Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device(s) under the Federal Food, Drug and Cosmetic Act.

Contact

Philip B. Lawin, Ph.D.
President
Brennen Medical
1290 Hammond Road
St. Paul, MN 55110
Contact Telephone Number 651-429-7413

Date

October 8, 2002

Phillip B. Lawin, Ph. D.
President

Date: 10/9/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Brennen Medical, Inc.
Phillip B. Lawin, Ph.D.
President
1290 Hammond Road
St. Paul, Minnesota 55110

Re: K021835
Trade/Device Name: Brennen Medical Surgical Mesh, GlucaMesh/Glucatex
Regulation Number: 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: August 8, 2002
Received: August 12, 2002

Dear Dr. Lawin:

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.

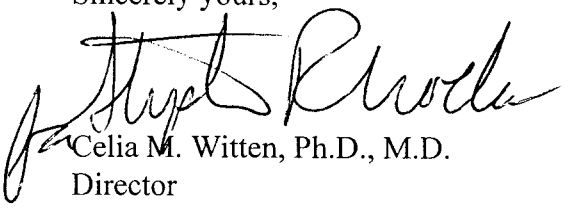
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



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

K 021835

510(k) Number (If Known):

Device Name: Brennen Medical GlucaMesh Surgical Mesh

INDICATIONS FOR USE:

Glucamesh™/Glucatex™ Surgical Mesh is intended for the use as a prosthesis in general surgery for surgical treatment of abdominal wall reinforcement, hernia repairs, eventrations, rectal and genitourinary prolapse. The meshes are biocompatible and not biodegradable. The device is intended to be implanted by a qualified surgeon.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021835