K970561

510(k) SUMMARY
Organogenesis Inc.
GraftPatch®

AUG - 1 1997

1. DATE PREPARED

January 23, 1997

2. SUBMITTER

Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

3. CONTACT

Joel T. Cademartori, P.E.
Vice President of Regulatory Affairs, Quality Assurance and Control
Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

Telephone: (617) 575-0775
Facsimile: (617) 575-0440

4. DEVICE NAME

GraftPatch®

5. DEVICE CLASSIFICATION

Class II (21 CFR 878.3300)
Product Code: 79 FTM

6. DEVICE DESCRIPTION AND COMPARISON TO PREDICATE PRODUCTS

GraftPatch® is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists, e.g., hernia repairs. The device is composed of heat-laminated layers of crosslinked porcine collagen. GraftPatch® is similar in design, materials, function, and intended use to other surgical meshes which are currently in U.S. commercial distribution. Examples of other surgical meshes which have been cleared for commercial distribution include the Supple Peri-guard® by Bio-Vascular, Inc. (K923657), and Vicryl surgical mesh by Ethicon, Inc. (K810218).

Determination of substantial equivalence for this product was based on descriptive information about the design, materials, and intended use of the device. Animal implant studies were performed to confirm the functionality of the device. Biocompatibility testing was conducted on the device material in conformance with Tripartite and ISO 10993 recommendations. Results of all testing demonstrated that GraftPatch® Surgical Mesh is both suitable for its intended use and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joel T. Cademartori, P.E.
Vice President of Regulatory Affairs
Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

Re: K970561
Trade Name: GraftPatch®
Regulatory Class: II
Product Code: FTL
Dated: June 23, 1997
Received: Jun 25, 1997

AUG - 1 1997

Dear Mr. Cademartori:

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.

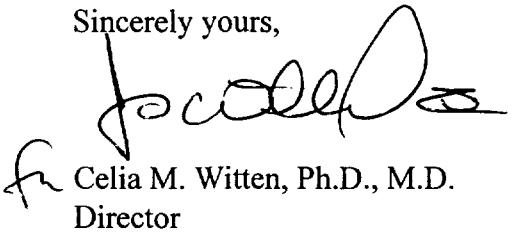
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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,



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

Enclosure

510(k) Number (if known): K970561

Device Name: GraftPatch®

Indications For Use:

The GraftPatch® is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970561

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)