

K052100

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AUG 11 2005

SECTION 1 510(k) Summary

SUBMITTED FOR:

Proxy Biomedical, Ltd.

Unit 6D, Mervue Business Park

Galway, IRELAND

Contact Person: Peter Mulrooney, Quality Assurance Manager

Tel: +353 (0)91 709161

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Submitted by:

Elaine Duncan, M.S.M.E., RAC

President, Paladin Medical, Inc.

PO Box 560

Stillwater, MN 55082

715-549-6035

715-549-5380

CONTACT PERSON:

Elaine Duncan

DATE PREPARED:

August 1, 2005

TRADE NAME:

MOTIFMESH™ Soft Tissue Patch

COMMON NAME:

urgical Mesh

SUBSTANTIALLY EQUIVALENT TO: MOTIFMESH™ Soft Tissue Patch with the sinusoidal cell opening is substantially equivalent to the MOTIFMESH™ Soft Tissue Patch with the hexagonal shape previously cleared under K050678.

DESCRIPTION of the DEVICE:

Proxy Biomedical MotifMesh™ Soft Tissue Patch is a non-absorbable, inert, sterile, porous surgical soft tissue patch produced from expanded polytetrafluoroethylene. The implant has a structure characterized by closed cell openings in a high strength film. The construction allows the soft tissue patch to be stretched in both directions, to accommodate and reinforce tissue defects. The Soft tissue patch measures 0.006" +/- 0.001" in thickness and exhibits high burst strength and tensile strength. Use of MOTIFMESH™ Soft Tissue Patch allows a fibroblastic response through the interstices of the implant, forming a fibrous wall.

INDICATIONS FOR USE:

MOTIFMESH™ Soft Tissue Patch is intended to assist in the repair and/or reinforcement of hernia and other fascial defects requiring the additional support of a nonabsorbable implant during and after wound healing.

SUMMARY of TESTING:

Bench test data reveal MOTIFMESH™ Soft Tissue Patch has mechanical and material characterization values that are substantially equivalent to the predicate devices. The biocompatibility test results show that the material used in the design and manufacture of the device is non-toxic and non-sensitizing to biological tissues consistent with their intended use.



AUG 11 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Proxy Biomedical, Ltd.
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, Minnesota 55082-0560

Re: K052100

Trade/Device Name: Modification to Motif Mesh Soft Tissue Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: August 1, 2005
Received: August 3, 2005

Dear Ms. Duncan:

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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink that reads "Barbara" followed by a stylized flourish, and the word "for" written below it.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052100

Device Name: Modification to Motif Mesh Soft Tissue Patch

Indications For Use:

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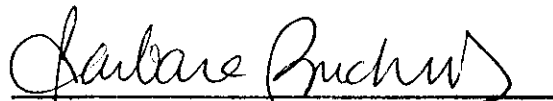
Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 807 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 General, Restorative,
and Neurological Devices**

510(k) Number K052100

Page 1 of _____