MAR 2 0 2007

K063556

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510(k) Summary of Safety & Effectiveness

Submitter:	PM Devices Inc. 13700 Mayfield Place, Unit 2135 Richmond, British Columbia V6V 2E4 Canada Phone: (604) 270-4344 Fax: (604) 270-4384
Contact Person:	Tim Verspagen
Device Name:	PeriPatch Aegis
Common Name:	Surgical Mesh
Classification Name:	Surgical Mesh (Product Code: FTM)
Predicate Devices:	1) PeriPatch Sleeve (K033985) 2) Peri-Strips Staple Line Reinforcement – Sleeve Configuration (K992537)
Device Description:	The PeriPatch Aegis is intended be used as a surgical patch material to reinforce surgical staples during stapling procedures. The PeriPatch Aegis device assembly consists of a strip of buttress material, a cartridge which mates the device to the endoscopic stapler, and finally a loader which assists the user to place the device on to the stapler.
Intended Use:	The PeriPatch Endo-Sleeve is intended for reinforcing staples and suture lines during a number of resection techniques - surgical repair of tissue deficiencies such as: • Lung resections • Biopses • Lobectomies • Gastric banding • Abdominal and thoracic wall repair
Technological Comparison & Performance Data:	Tissue functional testing was carried out in accordance with the *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.* The test results demonstrate suitable material properties for the indications of the device. The PeriPatch Aegis is substantially equivalent to the predicate devices as it has similar indications for use, similar materials and similar technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PM Devices, Inc.
% Mr. Tim Verspagen
Regulatory Affairs Director
13700 Mayfield Place, Unit 2135
Richmond, British Columbia
V6V 2E4 Canada

MAR 2 0 2007

Re: K063556
Trade/Device Name: PeriPatch Aegis
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: February 23, 2007
Received: February 26, 2007

Dear Mr. Verspagen:

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.

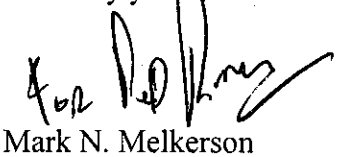
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K063556

Statement of Indications for Use

510(k) Number (if known): K063556

Device Name: PeriPatch Aegis

Indications for Use:

The PeriPatch Aegis is intended for reinforcing staples and suture lines during a number of resection techniques - surgical repair of tissue deficiencies such as:

- Lung resections
- Biopses
- Lobectomies
- Gastric banding
- Abdominal and thoracic wall repair

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 General, Restorative, and Neurological Devices

510(k) Number K063556