K063671

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510(k) Summary

Submitted on behalf of:

AUG 16 2007

Company Name: **Minnesota Medical Development, Inc. (MMDI)**
Address: **14305 21st Avenue North, Suite 100**
Plymouth, MN 55447
Telephone: **763-354-7100**
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by: **Elaine Duncan, M.S.M.E., RAC**
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: **715-549-6035**
Fax: **715-549-5380**

CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **December 8, 2006**
TRADE NAME: **REBOUND HRD™ hernia mesh device**
COMMON NAME: **hernia mesh**
CLASSIFICATION NAME: **surgical mesh**
PRO CODE: **FTL**

SUBSTANTIALLY EQUIVALENT TO:
VITAMESH™ MacroPorous PP Surgical Mesh K060520 and K963141 Kugel Hernia Patch

DESCRIPTION of the DEVICE: **The Rebound HRD™ (Hernia Repair Device) is a self-expanding Nitinol framed/surgical mesh designed for the repair of both inguinal and ventral hernias. The Rebound HRD™ is designed for placement, between the fascia and fully closed peritoneum, so that it covers the direct and indirect space with at least a 15mm margin beyond the edges of the hernia defect. The Rebound HRD™ conforms to the anatomy while providing stability; eliminating the need for anchoring. The super-elastic, multi-strand, Nitinol frame allows the device to be folded into the supplied 10mm loading cannula (supplied in the product package) and inserted laparoscopically through a 10-12mm access port. it may also be placed via an open incision approach using the same dissection and positioning methods described for the laparoscopic technique. The Rebound HRD™ is supplied sterile and is designed as a single use device. It is manufactured in several shapes to accommodate different hernia types, anatomies and surgeon preference.**

INDICATIONS FOR USE: **REBOUND HRD™ is intended to assist in the repair and/or reinforcement of hernia or other soft tissue defects where weakness exists and where the support of a nonabsorbable material is preferred.**

SUMMARY of TESTING: **The polymer mesh is the same mesh as submitted in a predicate submission. Therefore the testing concentrated on questions of potential new risks from adding the wire frame. Confirming biocompatibility testing demonstrated that processing and additional materials do not alter the excellent biocompatibility of the basic mesh. Testing included weld testing, burst strength testing on the assembly, deployment of the device through a cannula and fatigue testing. In addition, MRI compatibility testing was conducted to assure MRI compatibility. Animal testing demonstrated the device will stay in place, will stay together when implanted, can be detected via X-ray, and has tissue response typical for this type of implant. Instructions for use were evaluated as well.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2007

Minnesota Medical Development, Inc.
% Paladin Medical, Inc.
Ms. Elaine Duncan, M.S., RAC
President
P.O. Box 560
Stillwater, Minnesota 55082-0560

Re: K063671
Trade/Device Name: REBOUND HRD™ (Hernia Mesh Device)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 1, 2007
Received: August 2, 2007

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 (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

K063671

Indications for Use

510(k) Number (if known):

Device Name: REBOUND HRD™ (Hernia Mesh Device)

Indications For Use:

REBOUND HRD™ is intended to assist in the repair and/or reinforcement of hernia or other soft tissue defects where weakness exists and where the support of a nonabsorbable material is preferred.

Prescription Use ___X___ 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)

Mark N Milhauser

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

510(k) Number K063671