K080393

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MAR 13 2008

Section 5 – 510(k) Summary

Applicant:	Minnesota Medical Development, Inc. 14305 21st Avenue North, Suite 100 Plymouth, MN 55447
Contact Person:	Julie Bulver Senior Consultant, Alquest, Inc. Telephone: 763.588.9839 Fax: 763.2873836 Email: julieb@alquest.com
Date Prepared:	February 11, 2008
Trade Name:	REBOUND HRD™
Product Classification and Code:	21 CFR §878.3300, Surgical Mesh Class: II Product Code: FTL
Predicate Device:	REBOUND HRD™
Device Description:	The REBOUND HRD™ (Hernia Repair Device) is a self-expanding nitinol framed surgical mesh 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-stranded nitinol frame allows the device to be folded into a 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.
Intended 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 Technological Characteristics:	The device is manufactured of the same materials as the predicate device and introduces additional shapes and sizes with similar device characteristics as the predicate device. Device modifications were made in accordance with design control requirements. Design verification and validation activities were performed as identified during risk analysis.
Conclusion:	REBOUND HRD™ is substantially equivalent to the REBOUND HRD™ (K063671) in regards to the indications for use, the basic operating principle, materials, sterilization, packaging and shelf-life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

Alquest, Inc.
% Ms. Julie Bulver
Senior Consultant
4050 Olson Memorial Highway
Suite 350
Minneapolis, Minnesota 55422

Re: K080393
Trade/Device Name: REBOUND HRD™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 11, 2008
Received: February 13, 2008

Dear Ms. Bulver:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

K080393

Section 4 – Indications For Use Statement

510(k) Number (if known): K_____

Device Name:

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 (Part 21 CFR 801 Subpart D)	X	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 K080393