K083467

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Section 5 – 510(k) Summary

APR 2 3 2009

Applicant:	Minnesota Medical Development, Inc. 14305 21st Avenue North, Suite 100 Plymouth, MN 55447
Contact Person:	Julie Bulver Principal Consultant, Alquest, Inc. Telephone: 763.588.9839 Fax: 763.287.3836 Email: julieb@alquest.com
Date Prepared:	November 21, 2008
Trade Name:	REBOUND HRD®V
Product Classification and Code:	21 CFR §878.3300, Surgical Mesh Class: II Product Code: FTL
Predicate Device:	REBOUND HRD™
Device Description:	The REBOUND HRD V (Hernia Repair Device) is a self-expanding nitinol framed surgical mesh designed for placement directly over the hernia defect so that there is at least 4 cm of circumferential overlap of the hernia defect by the device. The REBOUND HRD V conforms to the anatomy while providing stability. 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 an appropriately sized access port. It may also be placed via an open incisional approach. The REBOUND HRD V is supplied sterile and is designed as a single use device. It is manufactured in three sizes to accommodate different hernia types, anatomies and surgeon preference.
Intended Use:	REBOUND HRD V 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:	REBOUND HRD V introduces additional shapes and sizes with similar device characteristics as the predicate device. The device is manufactured of the same frame materials as the predicate device. The mesh fabric material is made of PTFE. 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 V is substantially equivalent to the REBOUND HRD™ (K063671, K080393) 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

Minnesota Medical Development, Inc.
% Mr. Steve Nuss
Chief Marketing Officer
14305 21st Avenue, North Suite 100
Plymouth, Minnesota 55447

APR 23 2009

Re: K083467
Trade/Device Name: REBOUND HRD® V
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 20, 2009
Received: March 24, 2009

Dear Mr. Nuss:

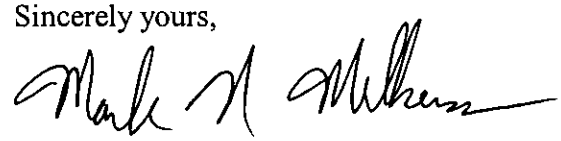
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083467

Section 4 – Indications For Use Statement

510(k) Number (if known): K 083467

Device Name:

Indications for Use:

REBOUND HRD® V 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)

Daniel Krause for MXM

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

510(k) Number K083467