510(k) Summary

MAY 11 2009

General Information

Submitter/Manufacturer Name/Address:	Alure Medical, Inc. 2445 Impala Drive Carlsbad, CA 92010
Alternate Manufacturing Location:	Alure Medical, Inc. 3637 Westwind Blvd., Suite B Santa Rosa, CA 95403
Establishment Registration Number:	Not Available
Contact Person:	Jasper Benke
Phone Number:	(707) 526-4400
Date Prepared:	October 17, 2008

Device Description

Trade Name:	Refine™ Support System
Generic/Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric, (21 CFR 878.3300, Product Code FTL)

Predicate Device Information

K080216 SupraMesh EXTRA™
K081069 INFINIT Mesh
K001122 Prolene™ Soft (polypropylene) Mesh

Product Description

The Refine™ Support System consists of a non-absorbable implant and a delivery system. The implant consists of a mesh and suture anchor. The device and the delivery system are delivered sterile and are for single use only.

Intended Use

The Refine™ Support System is indicated for reinforcement of soft tissue in plastic or reconstructive procedures.

Substantial Equivalence

Indications

Indications for use of the Refine™ Support System are similar to those of the predicate devices and have been substantiated by performance evaluations and comparison studies.

Technological Characteristics

In establishing substantial equivalence to the predicate devices, Alure Medical evaluated the materials, technology, and specifications of the subject and predicate devices. The technological characteristics are similar to many non-absorbable, implantable devices used in the reinforcement of soft tissue.

Performance

The Refine™ Support System is considered substantially equivalent in performance to the predicate devices. The device conforms to specifications and meets clinical user needs and intended uses. Bench studies and cadaver evaluations substantiate that the Refine™ Support System meets user needs and requirements for performance.

Summary of Safety and Effectiveness

Indications for use, technological characteristics, and performance evaluations of the Refine™ Support System show that the device is substantially equivalent to the predicate devices. Any differences are minor and do not raise any additional concerns regarding safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2009

Alure Medical Inc.
% Mr. Jasper Benke
Director, Regulatory Affairs, Quality
Assurance & Clinical Affairs
2445 Impala Drive
Carlsbad, California 92010

Re: K083102
Trade/Device Name: Refine™ Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: May 7, 2009
Received: May 8, 2009

Dear Mr. Benke:

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,

FOR

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

Enclosure

Indications for Use

510(k) Number: K083102

Device Name: Refine™ Support System

Indications for Use:

The Refine™ Support System is indicated for reinforcement of soft tissue in plastic or reconstructive procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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