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510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTED BY:	Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301
CONTACT PERSON:	Marla Kengen
DATE PREPARED:	October 12, 2005
CLASSIFICATION:	Polymeric Surgical Mesh (Product Code FTL) is a Class II device per 21 CFR 878.3300
COMMON NAME:	Polymeric Surgical Mesh
PROPRIETARY NAME:	POPmesh™
PREDICATE DEVICES:	K041362 Minimesh® Polyproylene Mesh (Mpathy Medical Devices Limited) K001122 Prolene® (Ethicon , Inc.) K002672 Vypro® II (Ethicon, Inc.)
DEVICE DESCRIPTION:	POPmesh™ is a non-absorbable polypropylene mesh constructed from knitted monofilaments of extruded polypropylene. POPmesh™ is constructed using a warp- knit process to a unique design that permits the mesh to be cut into any desired shape or size without unraveling. It maintains excellent isotropic properties arising from its knitted construction. POPmesh™ has the necessary strength, flexibility, durability and surgical adaptability. These properties permit the correct adaptation to the various stresses encountered in the body. The device is supplied sterile.

510(k) SUMMARY OF SAFETY & EFFECTIVENESS cont.

INTENDED USE: POPmesh™ may be used for the repair of abdominal wall hernia, including inguinal, femoral, and incisional uterovaginal prolapse and other fascial deficiencies that require support material. It may be used in open or laparoscopic abdominal procedures or for repair by the vaginal route.

POPmesh™ is a prescriptive device and should only be used by a licensed physician.

POPmesh™ has the same indications as its predicate device, Minimesh, Mpathy Corp.

TESTING: The patient contact materials used in this device are the same materials as the predicate detailed. Polypropylene has a long history of biocompatibility.

Testing has been performed on the POPmesh™ for biocompatibility as well as appropriate physical testing as outlined in the FDA Guidance Document "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2006

Caldera Medical, Inc.
c/o Ms. Marla Kengen
Project Leader
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301

Re: K053424
Trade/Device Name: Caldera Medical, Inc. POPmesh™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: January 27, 2006
Received: January 31, 2006

Dear Ms. Kengen:

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" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number: K053424

Device Name: Caldera Medical, Inc. POPmesh™

Indications for Use:

POPmesh™ may be used for the repair of abdominal wall hernia, including inguinal, femoral, and incisional uterovaginal prolapse and other fascial deficiencies that require support material. It may be used in open or laparoscopic abdominal procedures or for repair by the vaginal route.

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)

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

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