(A)

FEB 2 2 2006

Caldera Medical, Inc.
Caldera Large Pore Monofilament Polypropylene Mesh
K060004

510(k) Summary of Safety & Effectiveness

Date of Application:	December 30, 2005
Applicant:	Bryon L. Merade, CEO Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301 Tel: (866) 422-5337 Fax: (818) 879-6556
Contact:	Marla Kengen Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301 Tel: (866) 422-5337 Fax: (818) 879-6556 marla@calderamedical.com
Device Name:	Surgical Mesh (878.3300)
Trade Name:	Caldera Large Pore Monofilament Polypropylene Mesh
Common Name:	Surgical Mesh
Classification:	Class II
Registration Number:	9054589
Manufacturing Site:	Herniamesh s.r.l. Via Cirie 22/A San Mauro Torinese Torino, Italy 10099 Tel: +39 100 8227300 Fax: +39 011 8221396
Sterilization Site:	Bioster S.p.a. Via Cà Bertoncina 29 Seriate (BG), Italy 24068 Tel: +39 35 302729 Fax: +39 35 302515

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Device Description

The Caldera Polypropylene Mesh is made of monofilament polypropylene mesh. The Caldera Polypropylene Mesh is a sterile, single-use mesh used to provide additional support to weak muscle in specific urological, gynecological, or gastroenterological procedures.

It is provided in a variety of pre-formed sizes and shapes as well as a large size that can be cut to size by the physician.

The Caldera Polypropylene Mesh is available as the mesh only, without accessory items.

Statement of Indications for Use

The Caldera Polypropylene Mesh is a mesh sling implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral-colposuspension.

Testing

Testing has been performed on the Caldera Polypropylene Mesh 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: K060004
Trade/Device Name: Caldera Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: January 27, 2006
Received: January 30, 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

Additional Information Requested: K060004 Caldera Large Pore Monofilament Polypropylene Mesh

(A) - Revised

Indications for Use Form

510(k) Number: K060004

Device Name: Caldera Mesh

Indications For Use:

The Caldera Polypropylene Mesh is a mesh sling implant that is intended for the treatment of urinary incontinence resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral-colposuspension.

Prescription Use _X_ (per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

(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 K060004