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CALDERA MEDICAL

510(k) Summary

MAR 31 2009

Date of Summary:	December 12, 2008
Applicant:	Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301 P 866.422.5337 F 818.879.6556
Contact:	Mara Korsunsky Quality Assurance and Regulatory Affairs Manager P 818.879.6555 x 105 F 818.879.6556 E mkorsunsky@calderamedical.com
Device Name:	Surgical Mesh (878.3300)
Trade Name:	Ascend
Common Name:	Surgical Mesh
Predicate Device:	AMS Apogee Vault Suspension System K040537 AMS Perigee System K040623
Description of Device:	The Ascend Pelvic Floor Repair System consists of macroporous, monofilament, polypropylene mesh implants and a set of reusable introducers to facilitate mesh implant placement. The reusable introducers are available separately.
Intended Use of Device:	Ascend AC (anterior compartment) and Ascend PC (posterior compartment) are indicated for repair of pelvic organ prolapse, including anterior, posterior, vaginal vault and uterine prolapse.

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Summary of Technological Characteristics:	The mesh used in the Ascend device has been tested in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh and has been shown to be equivalent to the listed predicate devices. In addition, the other components have demonstrated substantial equivalence to the predicate devices in terms of mechanical testing and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Caldera Medical, Inc.
c/o Ms. Mara Korsunsky
QA/RA Manager
28632 Roadside Drive, Suite 260
AGOURA HILLS CA 91301

SEP 28 2012

Re: K083722
Trade/Device Name: Ascend
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: March 18, 2009
Received: March 19, 2009

Dear Ms. Korsunsky:

This letter corrects our substantially equivalent letter of March 31, 2009.

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 (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 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.

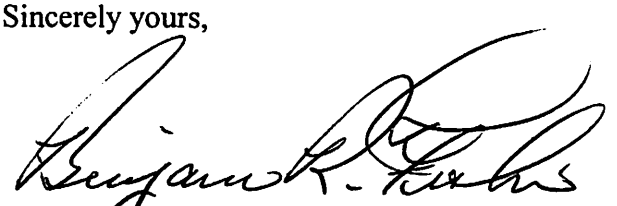
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K083722

Device Name: Ascend

Indications for Use:

Ascend AC and Ascend PC are indicated for repair of pelvic organ prolapse, including anterior, posterior, vaginal vault and uterine prolapse.

Prescription Use ■	AND/OR	Over-The-Counter Use ☐
(21 CFR 801 Subpart D)		(21 CFR 801 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 March 31, 2009

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

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