CALDERA MEDICAL

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510(k) Summary

AUG 16 2010

Date of Summary: June 16, 2010

Submitted by:

Submitter:	Caldera Medical, Inc.
Address:	28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301
Contact:	Vicki Gail, Manger QA/RA
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Device Name:

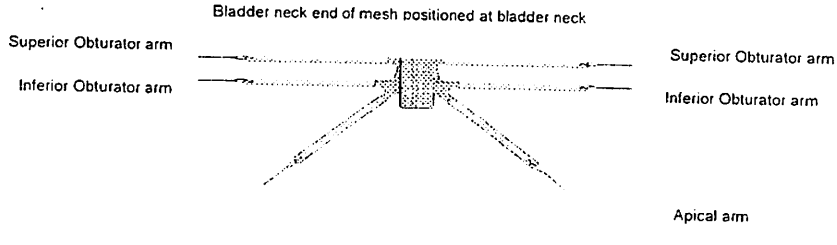
Trade Names:	Ascend® Blue Mesh AC Ascend® Blue Mesh PC
Common Name:	Surgical Mesh
Classification Name	Mesh, Surgical, Polymeric
Regulation No.	878.3300
Product Code	FTL
510(k) Number	K101462

Predicate Device: Ascend® Mesh (Caldera Medical, Inc.) K083722

Description of Device:

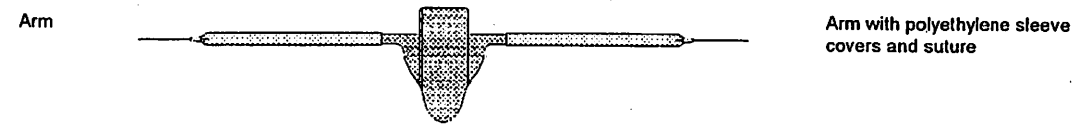
Ascend® Blue Mesh is designed to be used in the inpatient or outpatient surgery setting for use in women suffering from pelvic organ prolapse and is implanted using reusable Caldera Medical introducers, which are provided separately. Ascend® Blue Mesh is available in two different designs – one for anterior compartment defects (AC) and one for posterior compartment defects (PC).

Ascend® Blue Mesh AC design is composed of macroporous monofilament polypropylene warp knit mesh in a multi-zone construction, which includes blue polypropylene fibers in the central portion and clear polypropylene fibers on the remainder of the device. This formation improves the visualization of the central portion intraoperatively and postoperatively. The central portion provides direct support for the prolapsed organ, while the lateral arms will aid in delivery of the implant and provide tension free fixation. A visual reference of the product is provided below.



Ascend® Blue AC mesh implant

The Ascend® Blue product, PC configuration, consists of the same material components as the AC design: macroporous monofilament polypropylene warp knit mesh in a multi-zone construction, polyethylene sleeves, suture, and polyethylene tips.



Ascend® Blue PC mesh implant

Each arm is covered by a polyethylene sleeve to protect the arm and reduce tissue resistance during positioning. The suture, sleeves and tips are removed from the device once the unit has been surgically implanted, for this construction serves as a delivery mechanism only. The only component to remain within the body is a portion of mesh.

Intended Use of Device:

The Ascend® Blue AC (anterior compartment) and Ascend® Blue PC (posterior compartment) are indicated for repair of pelvic organ prolapse, including anterior, posterior, vaginal vault and uterine prolapse.

Technological Characteristics Comparison

The Ascend® Blue Mesh is a modification of the predicate mesh device comprised of the same knit pattern, sleeve and suture materials. The Ascend® Blue Mesh has the same intended use and does not change the fundamental scientific technology of the predicate device.

feature	Ascend® Mesh, K083722	Ascend® Blue Mesh
Indications for Use	Ascend® AC and Ascend® PC are indicated for repair of pelvic organ prolapse, including anterior, posterior, vaginal vault and uterine prolapse.	same
Design/ Materials	Pre-shaped, sterile, single use implant consisting of knitted large-pore monofilament polypropylene clear mesh with clear polyester heatshrink formed tips	Change: Central mesh is woven with blue tinted polypropylene yarn for improved visualization. Change: Color coded molded tips replace heat-shrink formed tips. Mesh weave pattern is unchanged.
Mesh color additive	none	21 CFR 74.3045
Sterility	SAL < 10^{-6}	same
Operating Principle	Supporting the pelvic region for treatment of pelvic organ prolapse	same
Shelf Life	60 months	18 months

feature	Ascend® Mesh, K083722	Ascend® Blue Mesh
Packaging and labeling	Tyvek inner and outer pouch, packaging card, IFU, labeling, packaging box and tamper-proof seal	same
Product Configuration	AC – anterior compartment PC – posterior compartment	same
Design	Pre-shaped, sterile, single use product	same
Mesh	Polypropylene monofilament	same
Sleeve	Polyethylene	same
Suture	Polyester braided suture, size 0	same
Junction	Polyester	PE

Performance Summary

In accordance with *FDA 's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh,* the results of bench, cadaver lab and validation testing has shown the Ascend® Blue Mesh to be equivalent to the predicate device.

The results of bench and cadaver testing demonstrated equivalent mesh characteristics, junction strength, and device function based upon its intended use to the predicate device.

The following parameters were assessed measured against the predicate device and found to be substantially equivalanet: Mesh thickness, pore size, mesh density area, flexural rigidity, tear resistance, burst strength, suture pullout, pyrogen levels.

In addition, the new Ascend® Blue Mesh has passed all testing requirements and demonstrated substantial equivalence to the predicate device in terms of aging, ISO 10993-1 tissue implant biocompatibility, ISTA Class C1 shipping challenge and sterilization.

Summary of Substantial Equivalence

The Ascend® Blue Mesh is safe and effective for its intended use and is substantially equivalent to the predicate device, Ascend® Mesh, also a product of Caldera Medical.

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.
% Ms. Vicki Gail
Manager, QA/RA
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301-6099

AUG 18 2010

Re: K101462
Trade/Device Name: Ascend® Blue
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: July 20, 2010
Received: July 22, 2010

Dear Ms. Gail:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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" (21CFR 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,

For Director, DSE

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

Indications For Use

510 (k) Number (if known): K101462

Device Name: Ascend® Blue

Indications for Use:

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

Prescription Use --X-- AND/OR Over the Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K101462