



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

April 6, 2015

Caldera Medical, Inc.  
Vicki Gail  
Manager QA/RA  
5171 Clareton Drive  
Agoura Hills, CA 91301

Re: K150016  
Trade/Device Name: Vertessa® Lite  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: OTO  
Dated: December 29, 2014  
Received: January 6, 2015

Dear Vicki 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

  
Herbert P. Lerner -S

for 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

## Statement of Indications For Use

### Indications For Use

510 (k) Number (if known): \_K150016\_\_\_\_\_

Device Name: Vertessa<sup>®</sup> Lite

Indications for Use:

Vertessa<sup>®</sup> Lite may be used for the repair of uterine or vaginal vault prolapse that require support material. It may be used in open or laparoscopic abdominal procedures.

Prescription Use --X--  
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use \_\_\_\_\_  
(Part 21 CFR 807 Subpart C)

*(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)*

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*Concurrence of CDRH, Office of Device Evaluation (ODE)*

## 510(k) Summary K150016

Date of Summary: April 6, 2015

Submitted by:

Submitter: Caldera Medical, Inc.  
Address: 5171 Clareton Drive  
Agoura Hills, CA 91301  
Contact: Vicki Gail, Manager QA/RA  
Phone: (818) 879-6555 x 102

Device Information:

Trade Name: Vertessa<sup>®</sup> Lite  
  
Classification: Class II  
OTO (mesh, surgical, gynecologic, for apical vaginal prolapse, transabdominally placed)  
21 CFR 878.3300 (surgical mesh)  
  
Predicates: Vertessa<sup>®</sup> Lite (K123337), Caldera Medical, Inc.

Description of Device:

Vertessa<sup>®</sup> Lite devices are designed to be used in women suffering from uterine or vaginal vault prolapse and are implanted or affixed using suture of the surgeon's choice. Vertessa<sup>®</sup> Lite devices are provided sterile and are comprised of macroporous monofilament polypropylene warp knit blue mesh. Vertessa<sup>®</sup> Lite will be available in a rectangular flat sheet mesh and rectangular strip mesh designs.

The flat sheet mesh designs are available in the following sizes: 8 x 16 cm, 8 x 18 cm, 8 x 20 cm, 8 x 22 cm, 8 x 24 cm, 8 x 26 cm, 10 x 16 cm, 10 x 18 cm, 10 x 20 cm, 10 x 22 cm, 10 x 24 cm, 10 x 26 cm, and 11 x 30 cm.

The strip mesh designs are available in the following sizes: 4 x 16 cm, 4 x 18 cm, 4 x 20 cm, 4 x 22 cm, 4 x 24 cm, 4 x 26 cm, 5 x 16 cm, 5 x 18 cm, 5 x 20 cm, 5 x 22 cm, 5 x 24 cm, 5 x 26 cm, and 6 x 30 cm.

Intended Use of Device:

Vertessa<sup>®</sup> Lite devices may be used for the repair of uterine or vaginal vault prolapse that requires support material. It may be used in open or laparoscopic abdominal procedures.

#### Technological Characteristics:

Vertessa<sup>®</sup> Lite devices submitted herein are a modification of the predicate mesh device, Vertessa<sup>®</sup> Lite (K123337). The modifications include available sizes, configuration (pre-cut strips), and a larger pore size. Vertessa<sup>®</sup> Lite devices submitted herein are comprised of the same blue mesh and the same mesh knit pattern as the predicate device. Vertessa<sup>®</sup> Lite submitted herein has the same intended use and same technological characteristics as that of its predicate device, Vertessa<sup>®</sup> Lite (K123337).

#### Performance Summary:

In accordance with the *FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh*, the following mesh characteristics were assessed: mesh thickness, mesh knit characteristics, pore size, mesh density, tensile strength, mesh stiffness (tensile and bending), tear resistance, and suture pullout strength. The results demonstrate that the Vertessa<sup>®</sup> Lite has comparative mechanical performance to the predicate device, Vertessa<sup>®</sup> Lite (K123337).

Vertessa<sup>®</sup> Lite has demonstrated biocompatibility as indicated per the FDA guidance document, *FDA Blue Book Memorandum #G95-1 Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing."*

In accordance with the FDA guidance document, Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry, FDA and the FDA consensus standard, ASTM F-1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, Vertessa<sup>®</sup> Lite has demonstrated appropriate sterilization validation and information to support a three-year shelf life.

#### Summary of Substantial Equivalence:

The performance data demonstrate that the Vertessa<sup>®</sup> Lite devices submitted herein are substantially equivalent to the predicate device, Vertessa<sup>®</sup> Lite (K123337) also a product of Caldera Medical, Inc.