## 510(k) Summary

Date of Summary: July 29, 2013

Submitted by:


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| Submitter: | Caldera Medical, Inc. |
| Address: | 5171 Clareton Drive<br>Agoura Hills, CA 91301 |
| Contact: | Vicki Gail, Manger QA/RA |
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Device Name:

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| Device Name: | Surgical Mesh (878.3300) |
| Trade Name: | Desara Mesh Sling |
| Common Name: | Surgical Mesh |
| Device Class: | Class II, Product Code OTN, 21 CFR 878.3300, Gynecologic, For Stress Urinary Incontinence, Female, Obstetrics/Gynecology Panel |
| Predicate Device: | Desara Mesh Sling, K072456, Caldera Medical, Inc. |

Description of Device:

The Desara Mesh Sling is a sterile, single-use pubourethral sling used to provide support in the pelvic region to treat stress urinary incontinence, mixed incontinence, and vaginal vault prolapse. The device is manufactured out of a monofilament polypropylene yarn, which is knitted into a mesh. The device has integral sleeves and sutures to assist the surgeon in placement of the device. The sleeves and sutures are removed after placement of the device.

Intended Use of Device:

The Desara Mesh is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Technological Characteristics

The new Desara Mesh is a modification of the predicate mesh device, with the same intended use and does not change the fundamental scientific technology as the predicate device.

Performance Data Summary

The biocompatibility tests conducted for the new Desara mesh were selected in accordance to ISO 10993, *Biological Evaluation of Medical Devices Part I: Evaluation and Testing standards* and all test results were passing.

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 new Desara Mesh device to be substantially equivalent to the predicate device.

Summary of Substantial Equivalence

The new Desara mesh is safe and effective for its intended use and is substantially equivalent to the predicate device, Desara 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 Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Caldera Medical, Inc.
% Vicki Gail
Quality and Operations Manager
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301

Re: K101169
Trade/Device Name: Desara® Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated (Date on orig SE ltr): April 23, 2010
Received (Date on orig SE ltr): April 26, 2010

Dear Vicki Gail,

This letter corrects our substantially equivalent letter of May 20, 2010.

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 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. 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,

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

# Indications for Use

**510(k) Number (if known): K101169**

**Device Name:** Desara® Mesh

**Indications for Use:**

The Desara® Mesh is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

| Prescription Use [X] (21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use [ ] (21 CFR 801 Subpart C) |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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