CALDERA MEDICAL

JUL 0 1 2014

510(k) Summary

Date of Summary:	March 28, 2014
Applicant:	Caldera Medical, Inc. 5171 Clareton Drive Agoura Hills, CA 91301 P (818) 879-6555 F (818) 879-6556
Contact:	Vicki Gail QA/RA and Operations Manager P (818) 483-7602 F (818) 736-9083 E vgail@calderamedical.com
Trade Name:	Desara® Blue OV Desara® Blue SS
Device Class:	Class II
Product Code:	OTN
C.F.R Section:	21 CFR 878.3300
Common Name:	Surgical Mesh
Product Code Name:	Mesh, surgical, synthetic, urogynecologic, for stress urinary incontinence, retropubic or transobturator
Classification Panel:	Obstetrics/Gynecology Panel
Predicate Device:	Desara® and Desara® Blue, K132069

Description of Device:
Desara® Blue OV and Desara® Blue SS devices are sterile, single-use mid-urethral slings used to provide support in the pelvic region to treat stress urinary or mixed incontinence. The devices are manufactured out of monofilament polypropylene yarn, which is knitted into a mesh. The devices have integral sleeves, tips and sutures to assist the surgeon in placement of the mesh, which are removed after placement of the device. Desara® Blue OV and Desara® Blue SS are designed to work with Caldera Medical's reusable introducers, which utilize a Universal Connection System offering surgeons the flexibility to choose their preferred surgical approach.

Desara® Blue OV incorporates an overlapping sleeve design as an alternative to the centerline sleeve gap utilized in the predicate devices, Desara® and Desara® Blue, K132069. Desara® Blue SS incorporates a shorter suture length than that of the predicate devices, Desara® and Desara® Blue, K132069.

Intended Use of Device:
Desara® Blue OV and Desara® Blue SS devices are 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.

CALDERA MEDICAL

Summary of Technological Characteristics
Desara® Blue OV and Desara® Blue SS devices submitted herein contain changes in the lengths of limited contact materials to add two additional device design options to the Desara® product family. Desara® Blue OV incorporates an overlapping (longer) sleeve design and Desara® Blue SS incorporates a shorter suture length design.

Desara® Blue OV and Desara® Blue SS are the same shape, overall size, comprised from the same raw materials and utilize the same mesh knit pattern and the same fundamental scientific technology as that of the predicate device, Desara® Blue (#K132069).

Performance Summary
Desara® Blue OV and Desara® Blue SS submitted herein are comprised of the same mesh resin as that of the predicate device, Desara® Blue (K132069) and the reference device, Ascend® Blue, (#K101462), also products of Caldera Medical. 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, flexural rigidity, tear resistance, burst strength, suture pullout and pyrogen levels. Results of both mechanical bench and validation testing demonstrate equivalent device function based upon its intended use to the predicate device, Desara® Blue, (#K132069). The change in sleeve length with an overlapping feature in Desara Blue OV and the shortened suture length in Desara Blue SS are minor dimensional changes to limited contact materials of the device. Bench testing was completed to assess sleeve removal and suture detachment when compared to the predicate device, Desara® Blue, (#K132069). The testing data met the predefined acceptance criteria and demonstrated the sleeve removal and suture detachment forces to be substantially equivalent to the predicate device, Desara® Blue, (#K132069).

Desara® Mesh (#K112609) and Ascend® Blue, (#K101462) were used as a reference for Desara® Blue OV and Desara® Blue SS devices for biocompatibility since they are comprised of the same materials. Desara® Mesh (#K112609) and Ascend® Blue, (#K101462) have passed all biocompatibility testing as indicated per the FDA guidance documents, *FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 3. Biocompatibility* and FDA *Draft Guidance Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing"*, dated April 23, 2013.

Testing documentation from Desara® Blue (#K132069) and Ascend® Blue, (#K101462) was used to support the shelf life and transportation of Desara® Blue OV and Desara® Blue SS and was performed in accordance with the *FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 4. Labeling* and FDA Consensus standard, *ASTM F-1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* as the devices are comprised of the same materials and utilize the same packaging, manufacturing and sterilization processes as that of Desara® Blue (#K132069).

Desara® Blue OV and Desara® Blue SS devices submitted herein were validated for EtO sterilization in accordance with FDA Guidance, *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA* and *AAMI TIR 28:2009, Product Adoption* and *Process Equivalence.*

Summary of Substantial Equivalence
The conclusions drawn from the non-clinical testing demonstrate that Desara® Blue OV and Desara® Blue SS submitted herein are substantially equivalent to the predicate device, Desara® Blue (#K132069).

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

July 1, 2014

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

Re: K140843
Trade/Device Name: Desara® Blue OV and Desara® Blue SS
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: May 30, 2014
Received: June 2, 2014

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" (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 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,

Benjamin R. Fisher -S

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

CALDERA MEDICAL

Indications for Use

510(k) Number (if known): K140843

Device Name: Desara® Blue OV
Desara® Blue SS

Indications for Use:

Desara® Blue OV and Desara® Blue SS are 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2014.06.30 17:26:37 -04'00'