NOV 3 0 2011 K103418

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CALDERA MEDICAL

510(k) Summary

Date of Summary: July 12, 2011

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 Name:

Device Name:	Surgical Mesh (878.3300)
Trade Name:	Desara Mini
Common Name:	Surgical Mesh
Device Class:	Class II, Product Code FTL, 21 CFR 878.3300, Surgical Mesh, Plastic and General Surgery
Predicate Devices:	Desara mesh, #K101169 MiniArc, #K073703

Description of Device:

The Desara Mini is a sterile, single-use pubourethral sling. The device is comprised of monofilament polypropylene yarn, which is knitted into a mesh, two self-fixating tips and two guiding suture loops at each end of the device. The device contains a visible mid-line marker to assist the surgeon in placement of the device.

The Desara Mini is available in one configuration and a reusable introducer is available separately.

Intended Use of Device:

Desara Mini is intended to be used in females to position a mesh for treatment of Genuine Stress Urinary Incontinence (SUI) and mixed incontinence resulting from urethral hypermobility. The mesh is placed transvaginally using a reusable introducer (sold separately)

Technological Characteristics

The Desara Mini utilizes a similar concept, mesh with self-fixating tips, as that of the predicate device, MiniArc. The Desara Mini is comprised of the same mesh and suture as the predicate device, Desara Mesh. Self-fixating tips are not contained in the predicate device, Desara Mesh.

The Desara Mini is a modification of the predicate devices, MiniArc, and Desara Mesh with the same intended use and does not change the fundamental scientific technology of the predicate device.

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Performance Data Summary

In accordance with the *FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)'s* the results of bench, cadaver lab and validation testing has shown the Desara Mini to be substantially equivalent to the predicate devices in its intended use, technological characteristics and performance.

The mesh component of the Desara Mini is comprised of the same mesh as the predicate device, Desara mesh, FDA 510(k) #K110169, also a product 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 weave characteristics, pore size, mesh density, tensile strength, mesh stiffness, flexural rigidity, tear resistance, burst strength, suture pullout and pyrogen levels. The Desara Mini mesh demonstrates substantial equivalence to the predicate device, Desara Mesh.

Desara Mini has 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 *Blue Book Memorandum #G95-1 Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".* The Desara Mini mesh demonstrates substantial equivalence to the predicate device, Desara Mesh.

In accordance with the FDA Guidance, *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry, FDA, 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,* Desara Mini has passed all testing requirements in terms of aging, shelf-life, transportation and sterilization and has demonstrated substantial equivalence to the predicate device, Desara Mesh.

Results of mechanical bench and functional cadaver testing demonstrate equivalent junction strength, device function and device performance (fixation tips, polypropylene mesh, suture loops and introducer) based upon its intended use to the predicate device, MiniArc.

The performance of the Desara Mini demonstrates that the device is as safe, and as effective, and performs at least as safely and effectively as the predicate devices, Desara Mesh and MiniArc.

Summary of Substantial Equivalence

The Desara Mini sling is safe and effective for its intended use and is substantially equivalent to the predicate devices Desara Mesh, also a product of Caldera Medical, Inc. and MiniArc, a product of American Medical Systems, Inc.

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

Ms. Vicki Gail
Manager, QA/RA
Caldera Medical, Inc.
5171 Clareton Drive
AGOURA HILLS CA 91301

SEP 28 2012

Re: K103418
Trade/Device Name: Desara Mini
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: November 14, 2011
Received: November 18, 2011

Dear Ms. Gail:

This letter corrects our substantially equivalent letter of November 30, 2011.

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.

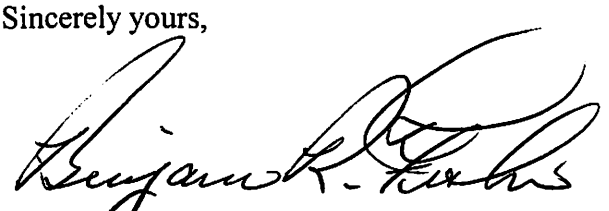
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

Indications For Use

510 (k) Number (if known): K103418

Device Name: Desara Mini

Indications for Use:

Desara Mini is intended to be used in females to position a suburethral mesh sling for treatment of Genuine Stress Urinary Incontinence (SUI) and mixed incontinence resulting from urethral hypermobility. The mesh is placed transvaginally using a reusable introducer (sold separately)

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103418