



May 4, 2018

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

Re: K172614
Trade/Device Name: Caldera Medical Surgical Mesh Instruments
Regulation Number: 21 CFR§ 884.4910
Regulation Name: Specialized Surgical Instrumentation for Use with Urogynecologic Surgical Mesh
Regulatory Class: II
Product Code: PWJ
Dated: April 3, 2018
Received: April 5, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -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)

K172614

Device Name

Caldera Medical Surgical Mesh Instruments

Indications for Use (Describe)

The Caldera Medical surgical mesh instruments are intended to be used in surgical procedures for the insertion and placement of Desara surgical mesh indicated for treatment of Genuine Stress Urinary Incontinence (SUI) and mixed incontinence.

Caldera Medical Outside-In introducers may be used with the following Desara implants:

Desara® (CAL-DS01), Desara® Blue (CAL-DS01B), Desara® Blue OV (CAL-DS01BOV), Desara® SL (CAL-DS01SL), Desara® Blue SS (CAL-DS01BS)

Caldera Medical Inside-Out introducers may be used with or without the Winged Guide Accessory with the following Desara implants:

Desara® (CAL-DS01), Desara® Blue (CAL-DS01B), Desara® Blue OV (CAL-DS01BOV), Desara® SL (CAL-DS01SL)

Caldera Medical Suprapubic introducers may be used with the following Desara implants:

Desara® (CAL-DS01), Desara® Blue (CAL-DS01B), Desara® Blue OV (CAL-DS01BOV), Desara® Blue SS (CAL-DS01BS)

Caldera Medical Transvaginal introducers may be used with the following Desara implants:

Desara® (CAL-DS01), Desara® Blue (CAL-DS01B), Desara® Blue OV (CAL-DS01BOV)

Desara® TV (CAL-DS01TV), Desara® Blue TV (CAL-DS01BTV) implants may only be used with Caldera Medical Transvaginal introducers, CAL-TV32

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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