November 10, 2021

Caldera Medical, Inc.
Vicki Gail
VP, Regulatory Affairs
4360 Park Terrace Drive
Westlake Village, CA 91361

Re: K211975
Trade/Device Name: Desara TV EZ 3.0 System, Desara Blue TV EZ 3.0 System
Desara TV EZ 2.7 System, Desara Blue TV EZ 2.7 System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTN, PWJ
Dated: October 8, 2021
Received: October 12, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number: K211975

Device Name
Desara TV EZ 3.0 System, Desara Blue TV EZ 3.0 System
Desara TV EZ 2.7 System, Desara Blue TV EZ 2.7 System

Indications for Use *(Describe)*

Desara TV EZ and Desara Blue TV EZ are intended to be used in females to position a mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

The 3.0mm or 2.7mm surgical mesh instruments are intended to be used in surgical procedures for the insertion and placement of Desara TV EZ and Desara Blue TV EZ surgical mesh indicated for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

| | |
|---|---|
| Date of Summary: | November 9, 2021 |
| Applicant: | Caldera Medical, Inc.<br>4360 Park Terrace Drive<br>Westlake Village, CA 91361<br>P: (818) 879-6555<br>F: (818) 879-6556 |
| Contact: | Vicki Gail<br>VP, Regulatory Affairs |
| Trade Name: | Desara TV EZ 3.0 System, Desara Blue TV EZ 3.0 System<br>Desara TV EZ 2.7 System, Desara Blue TV EZ 2.7 System |
| Device Class: | Class II |
| Product Code: | OTN<br>PWJ |
| Regulation Number: | 21 CFR§ 878.3300<br>21 CFR§ 884.4910 |
| Regulation Name: | Surgical Mesh |
| Common name: | Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic or Transobturator<br><br>Instrumentation, Surgical Mesh, Urogynecologic, Stress Urinary Incontinence |
| Classification Panel: | Gastroenterology/Urology |
| Predicate Device: | Desara® TV and Desara® Blue TV, 510(k) #K162201 (Primary)<br>Caldera Medical Surgical Mesh Instruments, #K172614 (Primary)<br>Desara® One, 510(k) #K191416 (Reference) |

Description of Device:

The Desara TV EZ and Desara Blue TV EZ Systems are comprised of sterile, single-use mid-urethral slings used to provide support in the pelvic region to treat female stress urinary or mixed incontinence and a stainless steel disposable introducer in either a 3.0mm or 2.7mm diameter. The devices are intended to be used in females, via the transvaginal surgical approach in the in-patient or out-patient clinical setting.

Desara TV EZ and Desara Blue TV EZ slings are manufactured out of monofilament polypropylene yarn, which is knitted into a mesh. The devices include mesh placement aides consisting of: integral sleeves over the mesh, a removable EZ tab midline

indicator and dilator tubes at each end of the device which attach to the 3.0mm or 2.7mm transvaginal surgical introducer for placement of the mesh. All placement aids are removed after the device is positioned and only the mesh portion of the device remains as a permanent implant.

Intended Use of Device:
Desara TV EZ and Desara Blue TV EZ are intended to be used in females to position a mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

The 3.0mm or 2.7mm surgical mesh instruments are intended to be used in surgical procedures for the insertion and placement of Desara TV EZ and Desara Blue TV EZ surgical mesh indicated for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Summary of Technological Characteristics
The Desara TV EZ devices differ from that of the predicate devices with the addition of a midline indicator tab and are packaged with a disposable instrument and are available in two sizes: 2.7mm and 3.0mm. The predicate devices were available in only one size and utilized a reusable instrument, available separate from the device.

The Desara TV EZ devices incorporate a change to the geometry of the dilator tube tip and diameter to accommodate the disposable instruments sizes, and remove the predicate designs suture loop and junction tip attachment to the dilator tube. Additionally, a slight tint was added to the protective mesh sleeve.

The Desara TV EZ and Desara Blue TV EZ implants are the same shape, overall size, are comprised from the same or similar raw materials, utilize the same mesh and utilize the same fundamental scientific technology as that of the predicate device, Desara® TV and Desara® Blue TV (#K162201).

The Desara TV EZ 3.0mm and Desara TV EZ 2.7mm surgical mesh instruments are the same general shape, similar overall size, comprised from the same or similar raw materials and utilize the same fundamental scientific technology as that of the predicate devices, Caldera Medical Surgical Mesh Instruments, (#K172614) and Desara One (#K191416).

Performance Summary
The Desara TV EZ and Desara Blue TV EZ implants utilize the identical mesh material and knit as that of the predicate device, Desara TV and Desara Blue TV (#K162201). 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.

- Biocompatibility

Desara TV EZ and Desara Blue TV EZ Systems biocompatibility testing is supported by passing testing results per the FDA guidance document *"Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" Guidance for Industry and Food and Drug Administration*, dated September 4, 2020 for both a permanent implant and limited use introducer.

- Mechanical/Performance Testing

The following testing was completed to demonstrate Desara TV EZ and Desara Blue TV EZ Systems function for their intended use:

- Dimensional characteristics
- Mesh thickness
- Mesh knit characteristics
- Pore Size
- Mesh Density
- Mesh Stiffness and Flexural Rigidity
- Mesh Tear resistance
- Junction Strength
- Suture Pull-Out
- Bend and Fatigue - Retropublic
- Torque and Tensile Strength

Results of both mechanical bench and validation testing demonstrate equivalent implant device function based upon the device intended use when compared to that of the predicate device, Desara TV and Desara Blue TV (#K162201).

Results of both mechanical bench and validation testing demonstrate equivalent introducer device function based upon its intended use when compared to that of the predicate devices Caldera Medical Surgical Mesh Instruments (#K172614).

- Shelf Life/Packaging

Shelf life including labeling, transportation and packaging integrity of Desara TV EZ and Desara Blue TV EZ Systems was validated per FDA *Shelf Life of Medical Devices*, dated April 1991, *BS EN 868-5, Packaging for terminally sterilized medical devices* and *ASTM F1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* and has met all pre-defined acceptance criteria and regulatory requirements as that of the predicate devices, Desara TV and Desara Blue TV (#K162201), Caldera Medical Surgical Mesh Instruments (#K172614) and Desara One (#K191416).

- Sterilization

Sterilization of Desara TV EZ and Desara Blue TV EZ Systems was validated to SAL $10^{-6}$ in accordance with the FDA Guidance, *Submission and Review of Sterility Information in Premarket (510(k)) Submissions for Devices Labeled as Sterile*, dated January 2016, ISO 11135, *Sterilization of health care products – Ethylene Oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices*, and AAMI TIR28, *Product Adoption and process equivalence for ethylene oxide sterilization* and has met all pre-defined acceptance criteria and regulatory requirements.

Summary of Substantial Equivalence

The conclusions drawn from the non-clinical and clinical tests demonstrate that Desara TV EZ and Desara Blue TV EZ Systems submitted herein are substantially equivalent to the predicate devices, Desara TV and Desara Blue TV (#K162201), Caldera Medical Surgical Mesh Instruments (#K172614) and Desara One (#K191416).