DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 23, 2015

Mederi Therapeutics, Inc.
% Michele Lucey
President
Lakeshore Medical Device Consulting, LLC
128 Blye Hill Landing
Newbury, NH 03255

Re: K152317
Trade/Device Name: Mederi Therapeutics Stretta® Catheter
Regulation Number: 21 CFR§ 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 25, 2015
Received: August 28, 2015

Dear Michele Lucey,

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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152317

Device Name

Mederi Therapeutics Stretta® Catheter

Indications for Use *(Describe)*

Intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of Gastroesophageal Reflux Disease (GERD).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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MEDERI THERAPEUTICS INC

Special
510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c)

Submitter Information:

Submitter's Name: Mederi Therapeutics Inc.

Sponsor Contact : Oleg Shikhman – Chief Operating Officer

Address: 800 Connecticut Ave
1E01
Norwalk, CT 06854

Telephone: 203-9 30-9900

Fax: 203-9 39-1088

Submitter's Regulatory Contact: Michele Lucey
Lakeshore Medical Device Consulting, LLC
128 Blye Hill Landing
Newbury, NH 03255
603-763-3455

Date Prepared: August 15, 2015

Device Trade Name: Mederi Therapeutics Stretta® Catheter

Common/Usual Name: Electrosurgical cutting and coagulation device and accessories

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulation Number: 21 CFR 878.4400

Class 2

Product Code GEI

Predicate Device K000245 - Conway Stuart Stretta System Catheter

Intended Use	Intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of Gastroesophageal Reflux Disease (GERD).
Device Description	The Stretta® Catheter is a single use monopolar electrosurgical device. The catheter connects to the Mederi RF Generator by means of a custom electrical connection. The catheter consists of a flexible shaft with a multi-arm basket at the distal end and a control handle at the proximal end. The catheter is introduced trans-orally. The catheter has depth of insertion

	indicators on the shaft to assist the user in inserting the device to the proper location. Inside the basket is a balloon that when inflated with sterile water or air to expands the basket during use. The basket arms support electrode needles which contact and penetrate esophageal tissue when the basket is expanded and the electrode needles are advanced. The basket arms also contain thermocouples to return temperature measurements to the generator during activation. The balloon is inflated by means of a syringe with an inline pressure relief valve.. The procedure, delivery of energy, occurs in several steps where the catheter is positioned, activated, rotated and repositioned during the course of the treatment
Technological Characteristics of the Device Compared to the Predicate Device	The Stretta® Catheter has the same technological characteristics as the predicate device, CMS Stretta Catheter. Both devices are sterile, single use catheters with the same intended use, principles of operation, energy type, and packaging. Both devices are similar in design and construction. Any differences do not introduce new questions regarding safety of performance. The modifications to the device include change in some materials, additional markings on the catheter shaft, replacement of bonded attachments with mechanical attachments, and change in location of certain electrical components.
Principles of Operation:	The Stretta® Catheter is a single use monopolar electrosurgical device. The catheter connects to the Mederi RF Generator by means of a custom electrical connection. Once the catheter is connected the device the user can activate the device to deliver radiofrequency energy. The device may be activated multiple times within the procedure to achieve the desired tissue effect.
Performance Data	Design verification and validation testing including *in vitro* functional testing (union strength, balloon/basket performance, thermocouple accuracy, system seal integrity, needle function, visual and dimensional verification), and biocompatibility testing were conducted to confirm that the modifications do not adversely affect safety and performance of the Stretta® Catheter.
Conclusion:	Based on the performance testing and comparison to the predicate device, the Stretta® Catheter is substantially equivalent to the Conway Stuart Stretta System Catheter.