

510(k) Summary

JAN 20 2011

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

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Date Prepared: October 8, 2010

Device Information

**Trade Name:** Mederi Therapeutics RF Generator Control Module  
**Common Name:** Electrosurgical, cutting & coagulation device and accessories  
**Regulation Name:** Electrosurgical cutting and coagulation device and accessories  
**Regulation Number:** 21 CFR 878.4400  
**Product Code:** GEI

Predicate Device(s):

- K000245 for the Stretta system (submitted by Conway Stuart Medical)
- K010210 for the Control Module Algorithm Enhancement for Model S500-ST and Model S400 (submitted by Curon Medical)
- K014216 for the Secca system (submitted by Curon Medical)

**Device Description**

The Mederi Therapeutics RF Generator Control Module is a Radio Frequency Generator which is used with the Stretta and Secca disposable hand pieces and accessories including irrigation tubing and foot pedal. The Mederi Therapeutics RF Generator Control Module is part of a therapeutic platform for treatment of various medical conditions with radiofrequency (RF) energy. Specifically, for the treatment of two conditions:

- Gastroesophageal reflux disease (GERD). Mederi’s devices used for treatment of this condition include the Mederi RF generator and the “Stretta” disposable kit.
- Fecal Incontinence (FI). Mederi’s devices used for treatment of this condition include the Mederi generator and the “Secca” disposable kit.

The Mederi RF Generator Control Module is a multi-channel electrosurgical generator that produces low power, radiofrequency (RF) energy using a sinusoidal waveform of 460 kHz. Needle tip and surface tissue temperatures are measured through disposable hand pieces during treatment by thermocouples located at the tip and base of the needle, respectively. The electrode tip temperature measurement regulates the output power in a closed-loop fashion to maintain the target temperature, while monitoring of the surface tissue temperature prevents overheating.

**Modified Device Description**

The modifications described in this submission include improvements to the design and performance of the RF Generator Control Module. Mederi Therapeutics is combining the functions of both previously marketed RF generators into a single compact RF generator utilizing the new hardware and software to improve the user interface and the overall performance of the system.

**Indication for Use**

The Mederi Therapeutics RF Generator Control Module is intended to for general use in the electrosurgical coagulation of tissue, specifically:

- the RF Generator Control Module and Secca disposable hand piece is intended for the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.
- the RF Generator Control Module and Stretta disposable hand piece is intended for the treatment of gastroesophageal reflux disease (GERD).

**Technological Characteristics**

**Performance Testing and Safety**

Specific performance tests and evaluations were conducted to assure the modified RF Generator Control Module performed as intended. Verification included Software Code

Review and performance testing on the Software Control Module (CM), Software CM functionality with Stretta Module, Software CM functionality with Secca Module, Audio Output, Equivalency to predicate devices, Energy and Impedance, Pump Function, Mechanical Systems, Environmental Conditions, Packaging (shipping and storage), Electrical Safety, Failsafe Specifications and Product Energy Delivery Integrity connected to a Secca or Stretta applied part (Disposable).

Verification testing of the Mederi Therapeutics RF Generator Control Module demonstrated that the device met the acceptance criteria.

#### Electrical Safety Testing

EMC/EMI and Electrical Safety Testing was conducted on the Mederi RF Generator Control Module and the Disposable Hand Pieces by Intertek and results demonstrated the RF Generator Control Module with the disposable Hand Piece meet the required safety standards.

#### Conclusion

Based on the same intended uses, similar technological characteristics, and performance characteristics, the Mederi Therapeutics RF Generator Control Module is substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Mederi Therapeutics, Inc.  
% Orchid Design  
Mr. Curtis Raymond  
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Shelton, Connecticut 06484

JAN 20 2011

Re: K103017

Trade/Device Name: Mederi Therapeutics RF Generator Control Module  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: January 10, 2011  
Received: January 12, 2011

Dear Mr. Raymond:

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.

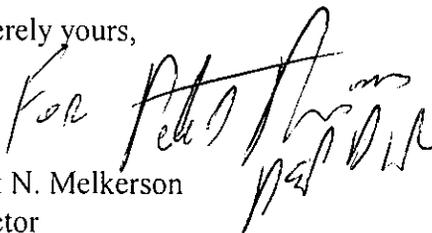
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 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" (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 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,

A handwritten signature in black ink, appearing to read "For Peter [unclear] Melkerson". The signature is written in a cursive style and is positioned above the typed name.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**  
(revised)

**510(k) Number:** K103017

**Device Name :** Mederi Therapeutics RF Generator Control Module

**Indications for Use 510K:**

The Mederi Therapeutics RF Generator is intended for general use in the electrosurgical coagulation of tissue, specifically:

- The Mederi RF Generator when used with the Secca Disposable Handpiece is intended for the treatment of bowel incontinence in patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.
- The Mederi RF Generator when used with the Stretta Disposable Catheter is intended for the treatment of gastroesophageal reflux disease (GERD).

Prescription Use:   X    
(Part 21 CFR 801 Subpart D)

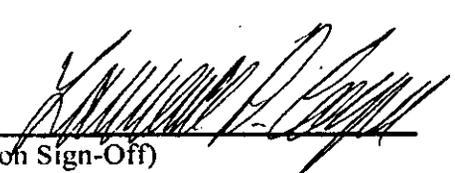
AND/OR

Over-the-Counter Use: \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K103017