DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 26, 2015

MedWaves Incorporated
Mr. Ted Ormsby
President/Chief Executive Officer
16760 West Bernardo Drive
San Diego, California 92127

Re: K143203
Trade/Device Name: AveCure™ Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: June 22, 2015
Received: June 27, 2015

Dear Mr. Ormsby:

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" (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 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*

K143203

Device Name

Device Name: AveCure™ Ablation System
Common Name: Microwave coagulation-ablation system and accessories
Classification Name: Electrosurgical cutting and coagulation device and accessories (21CFR 878.4400, Class II, NEY)

Indications for Use *(Describe)*

The MedWaves AveCure™ Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation-ablation of soft tissue.

The MedWaves AveCure™ Ablation System is not intended for use in cardiac procedures.

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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MedWaves Incorporated
16760 W Bernardo Drive
San Diego, CA 92127
August 26, 2015

510(k) Summary

510(K) submitter information

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Contact

Ted Ormsby
President/CEO
Phone: 760-807-1000
Email: tedormsby@avecure.com

The Device

Trade name:	AveCure® Ablation System
Common name:	Ablation system and accessories
Classification name:	Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories
Product Code:	NEY

Purpose of Submission

The purpose of this submission is to gain clearance for expanded indication for use.

Predicate Devices

MedWaves Microwave Coagulation/Ablation System:	K070356
MedWaves Microwave Coagulation/Ablation System:	K083537
NeuWave Medical Curtis 140™ Microwave Ablation System and Accessories:	K122217
Covidien Emprint™ Ablation System:	K133821

System Description

The MedWaves AveCure® Ablation System is designed to deliver ultrahigh radiofrequency (RF) through an antenna placed next to or embedded into soft-tissue for coagulating-ablating a volume of that tissue.

The MedWaves AveCure® Ablation System is composed of a durable generator-controller, and single-patient-use sterile accessories consisting of four antenna sizes and extension cable sets.

Each antenna-probe assembly is composed of one of the four antennas mounted at the distal end of one of many shaft configurations that are stiff, flexible or combination of both. The extension cable set is used to connect antennas to the generator controller. The material compositions of antennas and extension cables are nonmagnetic in nature and MRI safe. Therefore, the devices can be used in intraoperative, laparoscopic and percutaneous methods with CT, MR and Ultrasound imaging techniques to positions the antenna for ablation of soft-tissues.

The MedWaves AveCure® Ablation System is very efficient in transmitting RF power from the generator-controller to the antenna. With the low-power loss, the system does not need cooling pump, CO^2 or other mechanism to irrigate the antenna shaft and RF transmission lines for patient and user safety.

Indications for Use

The MedWaves AveCure® Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation-ablation of soft tissue.

The MedWaves Ablation System is not intended for use in cardiac procedures.

Technology Characteristics

The characteristics and operation of the MedWaves AveCure® Ablation System to a large extent is similar to the predicate group of devices. The system is powered by the 47-63Hz, 100-240VAC international current range, which is selected automatically. It is capable of generating 40 watts of radiofrequency (RF) power signal between 902 MHz and 928 MHz (ISM band), and composed of digital and analog circuits, and control firmware for user-interface and ablation processes controls. During the ablation processes, RF power is modulated to achieve and maintain programmed temperature set points between 60°C and 130°C for a programmed time interval. Frequency is scanned within the band and selected to minimize reflected power and maximizes antenna-tissue power transfer. Since its RF transmission loss is small, it uses relatively low power level of 40 watts and therefore, no need for a cooling mechanism. Therefore, the generator-controller is not blinded from seeing the tissue temperature at the antenna for safe and effective processes.

Performance Data

Characterization of the performance of the MedWaves AveCure® Ablation System to a large extent is similar to the predicate group of devices. The system meets all design specifications, design risk-analysis, and medical device standards for electrical safety-EMC (IEC 60601 2006 and 2007), biocompatibility (ISO 10993), sterility (ISO 11135 2007), and packaging shelf-life (ISO 11607 2006). The mechanical and coagulation-ablation performance ex-vivo and in-vivo meets the intended design and shows to be similar to the predicated devices.