November 25, 2020

MedWaves, Inc.
Theodore Ormsby
President/CEO
16760 West Bernardo Drive
San Diego, California 92127

Re: K192406/S002
Trade/Device Name: AveCure BT Microwave 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: October 20, 2020
Received: October 27, 2020

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. 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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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 *(if known)*
K192406

Device Name
AveCure BT Microwave Ablation System

Indications for Use *(Describe)*
The AveCure BT Microwave Ablation System is intended for:
• Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.
• Coagulation and ablation of tissue in bone during surgical procedures, including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

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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510(k) Summary

Date: November 25, 2020

Type of Submission: Traditional 510(k) Notification

510(K) submitter information:
MedWaves Incorporated
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Contact:
Theodore Ormsby
President/CEO
Phone: 760-807-1000
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Regulation: 21 CFR 878.4400. Electrosurgical Cutting and Coagulation Device and Accessories

Panel: General & Plastic Surgery

The Device:

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

The MedWaves' AveCure BT Microwave Ablation System is comprised of a microwave (915MHz ±13MHz) generator-controller, two antenna sizes mounted on the distal end of probes or catheters of various lengths, and flexibility, and a set of extension cables, one for microwave (MW) transmission and another for information communication between the antenna and the generator. The accessories (probes, catheters and extension-cable set) are supplied sterile and the generator-controller is the durable component of the system and is supplied non-sterile.

Predicate Devices:

Baylis Medical OsteoCool® V-3 RF Ablation System:	K161949: Class II, 21 CFR 878.4400, GEI

Reference Devices:

MedWaves AveCure Microwave Ablation System	K143203: Class II, 21 CFR 878.4400, NEY
MedWaves Microwave Coagluation/Ablation System	K070356: Class II, 21 CFR 878.4400, NEY

Indications for Use:
The AveCure BT Microwave Ablation System is intended for:

- Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.
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Technology Characteristics

MedWaves AveCure® BT Ablation System uses MW energy to treat soft-tissue tumor or tumor-like lesions. The system consists of MW generator-controller operating in the frequency range of 902MHz to 928MHz (915MHz ±13MHz ISM band), array of probes equipped with distally disposed antennas tuned to transfer energy to adjacent tissue in contact with it, and accessory extension cables connected them together. The microwave generator-controller is considered durable and reused, and the probes and accessories, which are provided sterile are considered single patient use and are disposed following a treatment. The generator-controller produces and manages appropriate power-train levers and durations to reach and maintain programmed temperature of tissue in contact with an antenna for the treatment durations. The AveCure BT Ablation System is based upon the systems cleared in K070356 and K143203, but only allows users to select from two antenna sizes with limited temperature settings.

The generator-controller is powered by 47-63Hz (50-60Hz ±3Hz), 100-240VAC international current range. It generates and controls up to 40 watts of microwave (MW) power signal from 902 MHz to 928 MHz (915MHz ±13MHz ISM band). The generator-controller is composed of digital and analog circuits, and control firmware for user-interface and ablation control factors such as temperature, power, frequency and duration. In standby mode, the operator can select antenna size (mini, small) being used, and the ablation parameters, such as, temperature set-point (60°C - 90°C) and duration (0 – 450seconds). During the ablation processes, MW power-train duration, frequency and level are automatically modulated to achieve and maintain tissue temperature in contact with antenna to a programmed set-point based upon the user input and feedback from a temperature sensor located at the antenna. The power frequency is scanned adjusted approximately once a second to minimize reflected-power (reverse-power) within the band for maximum antenna-tissue energy transfer. Since its MW transmission loss is small, it requires relatively low power level, up to 40 watts, and hence, 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 ablation processes.

The single-patient use antenna-probe assemblies are equipment with temperature sensor at the antenna for feedback to the generator-controller for power control. The antenna is used to detect reflected (reverse) power feedback signal during an ablation for generator-controller to use to select the frequency for optimum energy delivery to the nearby tissue. The generator-controller scans the allocated ISM band spectrum to select a frequency which minimizes the reverse-power levels for the most efficient energy transfer from the antenna to targeted tissue as the tissue conductivity and permittivity are modified from the temperature rise due to microwave power absorption, electrical effect and electromagnetic field interacting with the tissue.

Substantially Equivalent Discussion:

The features of the MedWaves AveCure BT Microwave Ablation (MWA) System are substantially equivalent to the predicate devices by Baylis Medical OsteoCool V-3 RFA System (K161949). Both systems deliver energy to a volume of targeted soft-tissue surrounding an active tip to raise its temperature for coagulate-ablation necrosis effect under temperature feedback control. The indication for use of the subject system is identical to the K161949. The ablation performance of the subject device is substantially equivalent to the predicate K161949. The subject device results in similar performance (tissue necrosis dimensions) in shorter cycles compared to the predicated device. Although the subject device comes in

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two antenna sizes versus four electrode sizes offered by the predicate device, the similar ablation performance dimensions can be obtained by overlapping applications. The subject device offers a greater variety of shaft length and flexibility. The subject system is based on the reference devices cleared under K143203 and K070356; it utilizes a subset of the antenna selections offered by the prior systems. The system meets all design specifications, design risk-analysis, and medical device standards for electrical safety-EMC (IEC60601-1:2006, IEC60601-1-2:2014, IEC60601-2-2:2009, and IEC 60601-2-6:2012), biocompatibility (ISO10993-1:2018), sterility (ISO11135-1:2014), Risk management ISO14971:2019, and packaging shelf-life (ISO11607-1: 2006). Applicable software verification and validation were completed per IEC 62304:2006.

Ablation Range comparison between the Predicate and Subject devices:

Comparison Summary:

Table A compares the ablation performance ranges in terms of volume, length, and widths. The ablation volume ranges from 7018mm^3 to the 320mm^3 for predicate and 7260mm^3 to the 320mm^3 for the subject. The ablation length (Z) of 31mm to 10mm for the predicate and 30mm to 10mm for the subject. The ablation width (X & Y) ranges from 22mm to 8mm for the predicate and 22mm to 8mm for the subject. The accumulated matching ablation cycle time ranges from 15minutes to 4minutes for the predicate and 7.5minutes to 0.5minutes for the subject. The subject K192406 device can achieve substantially equivalent ablation performances in 50% or less cycle times.

Ablation Performance Range Comparison Table A:

Category	Predicate OsteoCool V-3 RFA	Subject AveCure BT MWA	Difference	I/SE
Volume Max	7018mm^3 (15minutes)	7260mm^3 (7.5minutes)	3.4%	SE
Volume Min	320mm^3	320mm^3	0%	I
Length (Z) Max	31mm	30mm	-3%	SE
Length (Z) Min	10mm	10mm	0%	I
Width (X&Y) Max	22mm	22mm	0%	I
Width (X&Y) Min	8mm	8mm	0%	I

Volumes are estimates based on the calculation of volume for an ellipsoid.

I: Identical. SE: Substantially equivalent.

Conclusion:

The intended use of the subject device AveCure BT MW Ablation System is substantially equivalent to the predicate Medtronic (Baylis Medical) OsteoCool V-3 RF Ablation System K161949. The subject device identical to the MedWaves MWA systems approved under K070356 and K143203 with the following exceptions. The firmware configuration is modified to restrict its operating parameters for Mini and Small antennas. The power levels, temperature setting, and limits are configured to accommodate safe and effective bone ablation applications. The device configuration files and menu selection information which determines the applicable devices, and their operating control characteristics such as maximum power and maximum temperature are modified to reflect the new intended use. The foundation software

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remains the same as the previously cleared device under K143203 and K070356, but the narrower operating characteristics are implemented for the new indications for use by customizing the configuration firmware. The power levels and user temperature settings range are modified to match the single-patient use devices with the system for the intended use.

The regulation number and description, product Class, indications for use, user prescription, anatomic site, access methods, the principle of operation, mechanism of action, feedback mechanism, and mechanism of control are substantially equivalent to the predicate device. Bench testing in bone has demonstrated substantially equivalent ablation performance between the two systems. The predicate RFA and subject MWA systems can perform ablations of comparable volumes, lengths and widths. The subject device can achieve them in ablation cycle 50% shorter for the largest volume and 87.5% shorter for the smallest volume as described in the Substantial Equivalence discussion.

Unintended tissue ablation is important for both predicate and subject device to avoid. Data from experimental protocols show the subject ablation device behaves substantially equivalent to the predicate system in and around the bone and soft tissue structures, and the primary driver for heat distribution is through thermal conduction. All safety precautions derived from these studies have been incorporated into the labeling.

The differences in design and technology characteristics of the subject devices and predicate devices do not raise any new questions of safety and effectiveness and support the substantial equivalence. The subject device employs MW energy in the low microwave frequency range of 915MHz ±13MHz versus predicate, 465KHz ±3%, and due to their physical nature, the subject device employee antennas versus bipolar electrodes in the predicate. The predicate device active elements (electrodes) are in the form of semirigid probes whereas the subject device active elements (antennas) mounted as the distal tip of either semirigid probes or flexible catheters. Both applicators are inserted into the patient to deliver energy in order to raise temperatures for coagulation/ablation necrosis. Both RF and Microwave generators produce up to 40 watts of power, with the predicate device typically using 20 watts, and the subject device using 16 or 24 watts. However, due to the way the energy is delivered through the transmission line, the subject device does not require a cooling system along the shaft. The subject device produces electromagnetic field about its antennas and therefore no net current flow. The predicate RFA system and subject MWA system are substantially equivalent in their ablation performance, and both systems' ablation parameters can be adjusted as necessary to match one another.