February 22, 2019

Mectronic Medicale S.r.l.
Ms. Gloria Aloisini
Quality Manager
Via Orio al Serio, 15
24050 Grassobbio (BG), ITALY

Re: K183693
Trade/Device Name: Doctor Tecar
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: December 19, 2018
Received: December 31, 2018

Dear Ms. Aloisini:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

Digitally signed by David Krause -S
Date: 2019.02.22 08:29:41 -05'00'

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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183693

Device Name

Doctor Tecar

Indications for Use *(Describe)*

The Doctor Tecar device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.

Type of Use *(Select one or both, as applicable)*

[X] 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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K183693

510(k) Summary Pursuant to 21 CFR 807.92

Date: February 18, 2019
K183693

1. Submitted By:

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4. Product:

Doctor Tecar
(21CFR§878.4400) Class II
Doctor Tecar
Product code PBX

5. Common/Trade Name: Radiofrequency Induced Heat
Doctor Tecar

Description:

The Doctor Tecar generates a high frequency sinusoidal current with a monopolar mode of application using two electrodes. A fixed electrode is placed in contact with the patient and a hand held electrode is manipulated by a therapist. When both electrodes are in contact with a patient the electrical circuit is closed and RF therapy can be provided. The device can be operated in a capacitor resistive monopolar mode .

The product consists of a power console on a moveable trolley, LCD monitor, and accessories including capacitive resistive electrodes and multipolar electrodes. The unit can be adjusted to provide various levels of treatment frequency ranging from 460 KHz to 600 KHz.

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Intended Use:

The Doctor Tecar device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.

Substantial Equivalence/Technological Characteristics:

The Doctor Tecar device is substantially equivalent to the following device:

- Predicate device clearance: K162828
- Trade Name: Winback 3SE
- Company: WINBACK USA Corp

Both devices are cart mounted consoles with electrode accessories capable of operation in monopolar modes in the range of 460 kHz to 600 KHz radiofrequency.

Both devices operate in the same treatment range and voltage and feature intensity adjustments from 0 to 100%. Electrical safety and biocompatibility have been established for both devices. No direct comparison was made since there are no significant differences in operation and test results indicate identical safety.

The table below summarizes the equivalence of the devices.

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Predicate Device Comparison Table

Element of Comparison	**510(k) Device:** Doctor Tecar	**Predicate Device:** Winback 3SE K162828	**Explanation of Differences**
Regulation and Product Classification Code	21 CFR 878.4400 PBX	21 CFR 878.4400 PBX	None
Indications for Use	The Doctor Tecar device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.	The Winback Back 3SE devise is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation. The Winback 3SE massage device is intended to provide a temporary reduction in the appearance of cellulite.	No significant difference for radiofrequency device.
Electrode Shapes	Square and circular	Square and circular	Electrode shape is not a significant difference
Infrared Light	No	No	Identical
Vacuum (suction)	No	No	Identical
Treatment Activation	Finger selection on console	Finger selection on console	No significant difference
RF Type	Unipolar	Multipolar/Unipolar	No significant difference
RF Frequency	460 KHz – 600 KHz	300kHz – 1 MHz	No significant difference
Max RF Power	120 W	300 W	Max RF Power NO significant difference
Intensity Adjustment	0-100%	0-100%	Identical
Configuration	Cart mounted console with accessories	Cart mounted console with accessories	Identical
Patient Safety Switch	Yes	Yes	Identical
Standards Compliance	ISO10993, IEC60601-1, IEC60601-1-2 Compliant & IEC 60601-2-2: 2017 (6.0 Ed.) for use in conjunction with IEC 60601-1: 2005 AM1:2012	ISO10993, IEC60601-1 & IEC60601-1-2 Compliant	Identical

Summary of Testing:

The technological characteristics of the Doctor Tecar System has been verified based on assessments of electrical safety, performance, biocompatibility, software and usability. In addition, an assessment was done to demonstrate that the device effectively raises tissue temperature in a safe and efficient manner.

The following testing has been conducted with satisfactory results:

- Doctor Tecar Usability & Risk Management: Usability and Risk Management assessments were done using worse-case assumptions to verify user interface, safety features and satisfactory performance.
- Tissue Temperature Elevation Assessment: Studies were done in Italy using volunteers of varying skin colors to assess the capacity of the device to elevate tissue temperature in the treatment areas. The smallest and the largest electrodes were tested as well as the facial applicator electrode. Results indicated satisfactory safe therapeutic increases in tissue temperature.
- Biocompatibility: Samples of the tissue contacting probes were tested for cytotoxicity, sensitization and intracutaneous reactivity.
- Software Assessment: Software features were assessed in accordance with FDA software validation guidelines. Levels of Concern, User & System Requirements, Hazard Analysis, Software Requirements, Architectural Design, Software Validation & Testing were all addressed.
- Electromagnetic compatibility: EMC testing was done to evaluate emissions and immunity to electromagnetic fields in accordance with IEC 60601-1-2.
- Electrical safety: Full electrical safety testing was done in compliance with IEC 60601-1.
- Additional Electrical Testing: Additional electrical testing was done in compliance with IEC 60601-2-2: 2017 (6.0 Ed.) for use in conjunction with IEC 60601-1: 2005 AM1:2012

Substantial Equivalent Conclusion:

All testing has determined that Doctor Tecar is substantially equivalent to the predicate Winback 3SE device clearance: K162828. Both devices operate in the same treatment range and voltage and feature intensity adjustments from 0 to 100%. Electrical safety and biocompatibility have been established for both devices.