February 17, 2023

Mectronic Medicale S.r.l.
Gloria Aloisini
Quality Manager
Via Orio al Serio 15
Grassobbio, BG 24050
Italy

Re: K221043
Trade/Device Name: Doctor Tecar Plus, Doctor Tecar Smart
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: January 16, 2023
Received: January 18, 2023

Dear Gloria 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/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,

Colin K. Chen -S

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K221043

Device Name
Doctor Tecar Plus
Doctor Tecar Smart

Indications for Use *(Describe)*
The Doctor Tecar Plus and Doctor Tecar Smart devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation.

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

510(k) Number K221043
510(k) Application Traditional

CONTACT DETAILS

Mectronic Medicale S.r.l.
Via Orio al Serio, 15
24050 Grassobbio (BG)
ITALY
Phone: +39 035 656080, FAX: +39 035 65736
Official Correspondent
Gloria Aloisini
Mectronic Medicale S.r.l.
gloriaaloisini@mectronicmedicale.it
Phone: +39 035 656080, FAX: +39 035 65736

TRADE NAME

Doctor Tecar Plus
Doctor Tecar Smart
Common Name
Device Common name: Radiofrequency Device
Classification name
Classification name: Electrosurgical, cutting and coagulation accessories
Classification: Class II
Regulation Nos.: 21 CFR 878.4400
Product Codes: 79 PBX - Massager, Vacuum, Radio Frequency Induced Heat

PREDICATE DEVICE

The device under submission is substantially equivalent to the predicate devices:

- NuEra Tight RF Family, K200359, Bios S.r.l.

DEVICE DESCRIPTION

Doctor Tecar Plus and Doctor Tecar Smart are devices for diathermy. This therapy develops an increase in temperature in the area of the body which is treated through the passage of a particular electrical current. Through twin delivering modes, capacitive and resistive, the operator can set a specific treatment. The purpose of the treatment is to raise the temperature inside the tissue at a value maximum to 45 °C. The device is composed by a touch screen and a Multi-

Function knob (only Plus model) for managing all the device's functions, a plate, an handpiece for the delivery of radiofrequency energy, software and an on/off button to activate and deactivate the energy emission.

DEVICE INTENDED USE

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

PREDICATE DEVICE COMPARISON

The product specification, functionality, indications for use, and treatment parameters of the Doctor Tecar Smart and Doctor Tecar Plus are the same or very similar to the legally marketed predicate and reference devices. The technological similarities and differences between the doctor Tecar Smart/Plus and the predicate devices are described in the following table.

Feature	Predicate Device	Doctor Tecar Device	Comments
Regulation and product Classification Code	21 CFR 878.4400 PBX	21 CFR 878.4400 PBX	-
Intended Use / Indication For Use	The device is 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.	Same	-
Type of use	Prescription Use (21 CFR 801, Subpart D)	Same	-
Target Population	Whole population	Same	-
Anatomical Site	The devices are developed as portable devices indicated in therapy for muscular & skeletal pathologies.	Same	-
Clinical use	Prescription type	Same	-
Energy Used And/Or Delivered	250 W	PLUS : 200 VA SMART: 70 VA	No significant difference
Frequencies	470 kHz; 1 MHz; 2 MHz; 4 MHz ; 6 MHz	**PLUS :** 300 kHz - 448 kHz - 500 kHz - 750 kHz - 1 MHz - 1.2 MHz - 1.5 MHz	No significant difference

Feature	Predicate Device	Doctor Tecar Device	Comments
		SMART : 448 kHz - 750 kHz	No significant difference
Type of energy	Radiofrequency Waves	Radiofrequency Waves	-
Active Electrode	Round shape	Same	-
Neutral Electrode	Rectangular shape	Same	-
Design	Radiofrequency Energy with intensity adjustment from 0% to 100%	Same	-
Patient Safety Switch	Available	Same	-
Human Factors	Graphical user interface allows a better user experience and proper therapy selection	Same IEC 60601-1-6	-
Standards Met	IEC 60601-1; IEC 60601-1- 2 IEC 60601-2-2 IEC 60601-1- 6 IEC 62304 ISO 14971	CEI EN 60601-1 CEI EN 60601-1-2 IEC 60601-2-2 IEC 60601-1-6 IEC 62304 IEC 62366 UNI EN ISO 14971	No significant differences
Biocompatibility	IEC 60601 – 1 ISO 10993	IEC 60601 – 1 ISO 10993	-
Compatibility With The Environment And Other Devices	IEC 60601-1-2	IEC 60601-1-2	-
Sterility	N.A.	N.A.	-
Electrical Safety	IEC 60601-1	IEC 60601-1	-
Mechanical Safety	IEC 60601-1	IEC 60601-1	-
Chemical Safety	IEC 60601-1	IEC 60601-1	-
Thermal Safety	IEC 60601-1	IEC 60601-1	-

SAFETY TEST

The device has been tested and found in compliance with the following standards

- CEI EN 60601-1 Electro-medical equipment – General requirements for safety.
- CEI EN 60601-1-2 Electro-medical equipment - General requirements for safety – Secondary standard: Electromagnetic compatibility - Prescriptions and tests.
- IEC 60601-2-2 Medical electrical equipment. Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

- IEC 60601-1-6 Medical electrical equipment- Part 1: General requirements for basic safety and essential Performance. Collateral standard: Usability.
- IEC 62304 Medical device software – Software life-cycle processes.
- IEC 62366 Medical devices –Application of usability engineering to medical devices .
- UNI EN ISO 14971 Medical devices - Application of risk management to medical devices.

BENCH TEST

A test was performed to in order to to demonstrate the capability of Doctor Tecar Smart/Plus to maintain the temperature on the surface of the human skin. Based on the treatment recommendations, the test report demonstrates that Doctor Tecar Plus is capable of maintaining a skin surface temperature of 40°C – 45°C for 10-20 minutes after the temperature of the skin has reached 40°C. The test recorded actual skin temperature data to demonstrate safety when using the device as intended. The temperature test was done evaluating the device on 3 different people and for each people it was done the test on three different place on the body that are consistent with our instructions and indication for use. In this test we have included people with light and dark skin and people with different somatotype. For each person and for each place the test was performed in automatic mode, using electrodes and in manual mode with nine different applicators: small flat applicator, small rounded applicator, medium flat applicator, medium rounded applicator, big flat applicator, big rounded applicator, medium capacitive applicator, small bipolar applicator and big bipolar applicator. The temperature of the skin was measured every minutes for a treatment period of 12 minutes after the temperature of the skin has reached the 40°C. No discrepancies were found.

BIOCOMPATIBILITY

The Doctor Tecar Smart and Doctor Tecar Plus patient-contacting components have surfaces that, in accordance with the instructions for use, are categorized as ‘surface devices’, contacting ‘intact skin’, for a ‘limited’ time period (< 24 h), resulting in biocompatibility evaluation as follows, in accordance with Table A.1 of ISO 10993-1 and FDA guidance:

- Cytotoxicity: ISO 10993-5
- Sensitization: ISO 10993-10
- Irritation: ISO 10993-10

These patient-contacting components have all previously been cleared by FDA by means of successful 510(k) submissions. No further biocompatibility data is therefore included within this submission.

CONCLUSIONS

Doctor Tecar Plus and Doctor Tecar Smart generate radio frequency for treatment of selected tissues. They share the same basic characteristics and the same intended use as the predicate device. Moreover the safety and bench tests demonstrate that the the device is safe and performs as intended, and do not raise any concern about safety and effectiveness. There are no substantial differences between the product defined in this 510(k) submission and the predicate device that is,

they are essentially equivalents for the requested intended use. Therefore, the proposed device is substantially equivalent to the NuEra Tight RF Radiofrequency Device, cleared under 510(k) registration K200359.