October 15, 2021

El.En. Electronic Engineering S.p.A.
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, Firenze 50041
Italy

Re: K211091
Trade/Device Name: DEKA TIAC II
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: September 10, 2021
Received: September 13, 2021

Dear Paolo Peruzzi:

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,

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)*
K211091

Device Name
DEKA TIAC II

Indications for Use *(Describe)*
The DEKA TIAC II RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
The DEKA TIAC II massage device is intended to provide a temporary reduction in the appearance of cellulite.

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

DEKA TIAC II

Submitter:

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Date Summary Prepared:

October 15, 2021

Device Trade Name:

Deka TIAC II

Common Name:

Medical Radio Frequency and massage device

Classification Name:

Massager, vacuum, radio frequency induced heat (PBX)

Classification Number:

21 CFR 878.4400

Predicate Devices:

DEKA TIAC 1 (K183371)

Device Description:

The DEKA TIAC II is a medical device that used high frequency RF currents to produce a localized increase in temperature in subcutaneous tissue, for temporary relief of pain and muscle spasm and increase local circulation. The device has integrated massaging handpieces intended to provide a temporary reduction in the appearance of cellulite.

The DEKA TIAC II consists of the following main components:

• microprocessor-driven control unit

• high-frequency electromagnetic energy generator

• user interface with 10.4" color touch screen

• 2 RF handpieces for application of radiofrequency

• 2 integrated massaging balls handpieces

Contact quality monitoring system is present for monitoring of the contact quality under the RF handpiece electrodes.

The electrical specifications are 100-240Vac, 50/60Hz, 1500VA.

Indication for Use:

The DEKA TIAC II RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

The DEKA TIAC II massage device is intended to provide a temporary reduction in the appearance of cellulite.

Substantial equivalence discussion:

The DEKA TIAC II is substantially equivalent to the DEKA TIAC 1 (K183371).

Feature	**Proposed 510(k) Device** DEKA TIAC II	**Predicate Device** **K183371** DEKA TIAC 1
Device Trade Name	Proposed 510(k) Device DEKA TIAC 1	Proposed 510(k) Device DEKA TIAC 1

Feature	**Proposed 510(k) Device** DEKA TIAC II	**Predicate Device** **K183371** DEKA TIAC 1
Indications for Use	The DEKA TIAC II RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The DEKA TIAC II massage device is intended to provide a temporary reduction in the appearance of cellulite.	The DEKA TIAC1 RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The DEKA TIAC 1 massage device is intended to provide a temporary reduction in the appearance of cellulite.
Regulation number	21 CFR 878.4400: Electrosurgical cutting and coagulation	21 CFR 878.4400: Electrosurgical cutting and coagulation
Product Code	PBX	PBX
Device Technologies	• Application of the heat to the tissue via RF energy. • Mechanical Massaging of body parts	• Application of the heat to the tissue via RF energy. • Mechanical Massaging of body parts
RF Maximum output power	200W	120W
RF mode of operation	Bipolar	Bipolar
RF Output Frequency	2.45 GHz	2.45 GHz
Effective temperature	40-43°C	40-43°C
Contact quality monitoring system	YES	YES
Massage handpiece dimensions	Handpiece 1: Diameter: 68 mm Handpiece 2: Diameter: 78 mm	Handpiece 1: Diameter: 89 mm Handpiece 2: Diameter: 99 mm
Massage handpiece material	AISI 316	PPSU

The DEKA TIAC II has the same indications for use as the abovementioned predicate device, with same principle of operation and same performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

The following verification and validation activities have been performed on the modified device:

- Test according to AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, Cl:2009/(R)2012 and A2:2010/(R)2012 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- Test according to IEC 60601-1-2 Ed. 4 :2014– Medical electrical equipment – part 1-2: General Requirements for Basic Safety and Essential Performance– Collateral standard: Electromagnetic Disturbances – Requirements and tests.
- Test according to IEC 60601-2-6:2012+A1:2016- Medical electrical equipment - Part 2-6: Particular requirements for basic safety and essential performance of microwave therapy equipment.
- Non-clinical performance tests on ex-vivo animal tissue, in order to show that DEKA TIAC II RF device is able to maintain the tissue temperature in the range 40°C - 43°C for at least 5 minutes, at the maximum setting of RF output power (same test method used for the predicate device).
- Non-clinical human tests, in order to demonstrate that DEKA TIAC II RF device is capable of maintaining a skin surface temperature of 40º-45ºC for at least 10 minutes when using the device as intended (same test method used for the predicate device).
- Verification of biocompatibility of AISI 316 material

Non-clinical tissue-heating and human tests conducted on TIAC II are summarized in the table below.

Tests Performed	**Device Description/ Sample Size**	**Test method/ Applicable Standards**	**Acceptance Criteria**	**Unexpected Results/ Significant Deviations**	**Results**
Non-clinical - Tissue heating performance	Both Deep handpiece and Shallow handpiece tested on 20x20x5 cm ex-vivo pig muscle sample. Tissue sample immersed in a basin with water thermostated at 37 °C.	Worst case conditions for both handpieces: • Highest RF Power (200W) • Lowest skin cooling effect • Smallest treated area • Highest skin feedback Temperature.	• The sample temperature in the range 40-43°C for at least for 10 minutes in the active zone of the handpieces (hot spots); • skin surface increase in temperature not greater than 3°C. • temperature outside the hot spot never exceeding 40°C. • dissipation phase not increasing the temperature at the end of the treatment.	None	• Number of planned tests: 2 • Number of tests executed: 2 • Number of positive outcome: 2 (100%)

Non-clinical – human skin temperature maintaining performance	Both Deep handpiece and Shallow handpiece tested on 3 people of different skin types (Fitzpatrick I, III, IV) , on three areas of the body that are consistent with instructions and indications for use (abdomen , arm, thigh). The room was air-conditioned at a constant temperature of 22°C.	• Both handpieces tested at lowest (20W) and highest (200W) RF power • skin cooling 30°C • 15x15cm treated area • Feedback threshold 42°C • Smooth and continuous movements on the treatment area	• skin temperature is maintained in the range 40-45°C for at least 10 minutes • skin temperature doesn't exceed 45°C over the entire test period	None	• Number of planned tests: 36 • Number of tests executed: 36 • Number of positive outcome: 36 (100%)

The tests performed on ex-vivo animal tissue show that TIAC II RF device is able to heat the target tissue maintaining the tissue temperature in the range 40°C - 43°C for at least 10 minutes in the active zone of the handpieces, while not showing any significant increase in temperature out of the depth of action of the handpieces.

Non-clinical human tests show that that DEKA TIAC II RF device is able to keep the skin surface temperature in the range 40º-45ºC for at least 10 minutes when using the device as intended.

The non-clinical tests have been performed with the same test methods and acceptance criteria used for the predicate device.

Conclusion:

Based on the comparison of indications for use and the technological characteristics, and on the outcome of non-clinical performance data provided, we can conclude that DEKA TIAC II is as safe, as effective, and performs as well as the legally marketed predicate device.