March 28, 2023

Capenergy Medical S.L.
Pilar Sanchez
General Manager
Avinguda Mare de Déu de Montserrat, 41
Sant Joan Despi, Barcelona, Catalonia 08970
Spain

Re: K222260
Trade/Device Name: Capenergy C Equipment RF System - C25, C50, C100, C200, C300, C400, C500
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: January 29, 2023
Received: February 27, 2023

Dear Pilar Sanchez:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.28 12:52:43 -04'00'

Mark Trumbore, 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)*
K222260

Device Name
Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500

Indications for Use *(Describe)*
Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 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, and dermatological procedures.
The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.

Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 05 – 510(k) SUMMARY

DATE OF SUBMISSION: 2023-03-28

SUBMITTER NAME: Capenergy Medical S.L.
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Barcelona
Spain

CONTACT: Pilar Sánchez General Manager
TELEPHONE: +34 93 477 43 48
e-mail: pilar@capenergy.com

DEVICE TRADE NAME: Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500
COMMON NAME: Massager, Vacuum, Radio Frequency Induced Heat

REGULATION DESCRIPTION: General & Plastic Surgery
CLASS: Class II
REGULATION NUMBER: 21 CFR 878.4400
PRODUCT CODE: PBX
SUBSEQUENT PRODUCT CODE: GEI

PREDICATE DEVICE
Primary Predicate:

K191202	Capenergy - C50, C100, C200, C300, C400

Reference Predicate(s):

K171094	Thermi Reusable Non-invasive RF Electrode

DEVICE DESCRIPTION:
Capenergy C equipment's RF System - C25, C50, C100, C200, C300, C400, C500, including the hand piece, is a system generating RF energy with integral temperature and impedance feedback mechanism for procedures that require elevating tissue temperature. The Capenergy System constantly monitors the temperature and impedance of the target treatment tissue, automatically adjusting energy delivery to maintain effective and safe tissue heating.

Capenergy C equipment's RF System - C25, C50, C100, C200, C300, C400, C500 consists of an AC/DC power supply unit, RF generator, controller and user interface. The RF hand piece is

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connected to the console via a cable and a switch activates the energy delivery to the hand piece. The hand piece is comprised of conductive and capacitive electrodes.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:
In the establishment of substantial equivalence, Capenergy C Equipments RF Systems are compared with the following previously cleared devices:

Primary Predicate:

K191202	Capenergy - C50, C100, C200, C300, C400

Reference Predicate(s):

K171094	Thermi Reusable Non-invasive RF Electrode

The comparison of the subject device with the primary predicate device is summarized in the following table

CAPENERGY C EQUIPMENTS RF SYSTEMS
510(k) Premarket Notification Submission

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Device Characteristic	Subject Device	Primary predicate Device	Secondary Predicate Device
	Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 including Set of Capenergy Reusable Non-invasive RF monopolar Electrodes	The Capenergy C Devices - C50, C100, C200, C300, C400 K191202	Thermi Reusable Non-invasive RF Electrode K171094
FDA clearance	K222260	K191202	K171094
Regulation number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Product Code, Class	PBX Class II	PBX Class II	GEI Class II
IFU	Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 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	The Capenergy C Devices - C100, C200, C300, C400, C50, 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. The massage device provided is	Thermi Temperature Controlled Radiofrequency (RF) System are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

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	The massage device provided is intended to provide a temporary reduction in the appearance of Cellulite Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	intended to provide a temporary reduction in the appearance of cellulite	
Device Description	Capenergy RF generator produces an oscillating electric field in the antenna (electrode). The oscillating electrical field is transmitted to the surrounding soft tissue, causing heating of the tissue. A thermocouple in the electrode measures this increase in temperature and maintains a feedback loop to ensure a set point temperature in the tissue.	Capenergy RF generator produces an oscillating electric field in the antenna (electrode). The oscillating electrical field is transmitted to the surrounding soft tissue, causing heating of the tissue. A thermocouple in the electrode measures this increase in temperature and maintains a feedback loop to ensure a set point temperature in the tissue.	Thermi RF generator produces an oscillating electric field in the antenna (electrode). The oscillating electrical field is transmitted to the surrounding soft tissue, causing heating of the tissue. A thermocouple in the electrode measures this increase in temperature and maintains a feedback loop to ensure a set point temperature in the tissue.
RF Power	45 W +/-10% for a charge of 06-j530 ohms to 1 MHz	45 W +/-10% for a charge of 06-j530 ohms to 1 MHz	Up to 20 W
Internal Cut-Off	40-45ºC	40-45ºC	35-45ºC
Treatment Time	15-660 sec	15-660 sec	15-120 sec

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RF Frequency	Fixed values are established for the treatment time, percentage of power output and working frequency. There are four available options: 0.448 MHz +/-25% 0,8MHz +/-25% 1,0 MHz +/-25% 1,2 MHz +/-25%	Fixed values are established for the treatment time, percentage of power output and working frequency. There are three available options: 0,8MHz +/-25% 1,0 MHz +/-25% 1,2 MHz +/-25%	0.46 MHz
Waveform	Sinusoidal	Sinusoidal	Sinusoidal
Safety Class Protection	Class I – Type BF	Class I – Type BF	Class I – Type BF
Supply voltage and frequency	100–120/200–240V ± 10%, 50/60 Hz	100–120/200–240V ± 10%, 50/60 Hz	100–120/200–240V ± 10%, 50/60 Hz
Tissue impedance	50 -300 Ohm	50 -300 Ohm	50 -300 Ohm
Dimensions	170 x 220 mm x 250 mm 345x 420 mm x 220 mm 562 mm x 420 mm x 220 mm	345x 420 mm x 220 mm 562 mm x 420 mm x 220 mm	149x 327x322mm (5,9 ″ x 12,9 ″ x 12,7 ″)
Weight	3.5 - 22.5Kg	3.5 - 22.5Kg	15.8 lbs

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Compliance with voluntary standards / LAB tests performed	IEC 60601-1:2005 + /A1:2012 IEC 60601-1-2:2015 IEC 60601-1-6:2010 IEC 60601-2-2: 2017 IEC 62304:2006 ISO10993-1:2009	IEC 60601-1:2005 + /A1:2012 IEC 60601-1-2:2015 IEC 60601-1-6:2010 IEC 60601-2-2: 2017 IEC 62304:2006 ISO10993-1:2009	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-2-2 ISO10993-1:2009
Environmental conditions	Temperature: 10° to 40°C (+/- 20C) Relative humidity: less than 80%.	Temperature: 10° to 40°C (+/- 20C) Relative humidity: less than 80%.	Temperature: 10° to 40°C (+/- 20C) Relative humidity: less than 80%.

Table 1 Comparison with predicate and reference Device

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INTENDED USE / INDICATIONS FOR USE:

As established in the Indications for Use Statement:

> The Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 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
> The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.
> Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as diathermia radiofrequency device. Based on the bench tests conducted, the device demonstrated ability to reach and maintain therapeutic temperature (40-45ºC) on the surface of human skin for at least 10 minutes.
Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use, specifically including:

- Electrical safety
- Electromagnetic compatibility

In addition to the electrical safety testing performed, software verification and validation was conducted to IEC 62304: 2006 – Medical device software – Software Life-Cycle Processes, and FDA guidance on software validation. The results of this testing conclude the software has met these requirements.
Patient contacting materials have been evaluated according to the requirements of ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing, and confirmed to be biocompatible for their intended use.

CONCLUSIONS:

Based on the performance testing and comparison to predicate device, the Capenergy C equipments RF System - C25, C50, C100, C200, C300, C400, C500 with their set of Capenergy Reusable Non-invasive RF monopolar Electrodes are substantially equivalent in terms of technology, function and

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intended use, to the devices in predicate Capenergy C Devices - C50, C100, C200, C300, C400, and the device in predicate Thermi Reusable Non-Invasive RF Electrode (monopolar).