February 11, 2020

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

Re: K191202
Trade/Device Name: Capenergy - C100, C200, C300, C400, C50
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: October 31, 2019
Received: November 14, 2019

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191202

Device Name

CAPENERGY C Devices - C100, C200, C300, C400, C50

Indications for Use *(Describe)*

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 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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CAPENERGY	510(k) Premarket Notification	# Document: CAPENERGY - C 100, C 200, C 300, C 400, C 50

SECTION 05 - 510(k) Summary

510 (k) Submitter: Capenergy Medical S.L.
Pol. Ind. Fontsanta
Av. Mare de Deu de Montserrat, 41 bis Pje 1º derecha
08970 Sant Joan Despí
Barcelona – España

Establishment Registration Number: Not Established
Contact person: Pilar Sánchez
General Manager
Phone: +34 93 477 43 48
e-mail: pilar@capenergy.com

DATE OF SUBMISSION: 2020-02-10
SUBMITTER NAME: Capenergy Medical S.L.
SUBMITTER ADDRESS: Av. Mare de Deu de Montserrat, 41 bis Pje 1º derecha
08970 Sant Joan Despí
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CONTACT: Pilar Sánchez
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DEVICE TRADE NAME: CAPENERGY - C 100, C 200, C 300, C 400, C 50
COMMON NAME: Massager, Vacuum, Radio Frequency Induced Heat
CLASSIFICATION NAME: Massager, Vacuum, Radio Frequency Induced Heat
REGULATION NUMBER: 21 CFR 878.4400
PRODUCT CODE: PBX

PREDICATE DEVICE(S): Indiba Diathermia Radiofrequency Device - K161458
Winback Back 3SE - K162828

DEVICE DESCRIPTION:

The proposed device is an equipment for diathermy by energy transfer using radio frequency alternating electrical currents applied to the patient by using electrodes or plates.

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The RF current is coupled to the human body by means of an insulated or non-insulated electrode –the active accessory–, which together with the body and the return electrode –the passive plate– forms an electric circuit, which allows the passage of RF current through the body areas situated between the two electrodes.

The number of available channels on the different models of the CAPENERGY product range varies from one to four. When a model has several channels, these operate independently. Each channel has a keyboard that lets you manage the parameters of frequency and channel power. It also has two light columns that report the selected power level and a qualitative indication of the power delivered by the channel.

The user interface has a screen and a keyboard that allows you to manage several functions: timer, connected accessories management, state management, energy and temperature measurements and alarms. The user interface is organized in a menu system that makes it possible to choose between the different features available on the equipment.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, the CAPENERGY devices is compared with the following previously cleared devices:

- Indiba Diathermia Radiofrequency Device (K161458)
- Winback Back 3SE (K162828)

Comparison of the proposed devices with the predicate devices is summarized in the following table:

ELEMENT OF COMPARISON	Primary Predicate Indiba Diathermia Radiofrequency Device (Indiba USA Inc.)	Reference predicate device Winback Back 3SE (Winback USA Corp)	Subject Device CAPENERGY - C100, C200, C300, C400, C50 (Capenergy Medical S.L)
REGULATORY DATA			
Regulatory Class	Class II	Class II	Class II
Classification name	Electrosurgical, cutting and coagulation and accessories	Electrosurgical, cutting and coagulation and accessories	Electrosurgical, cutting and coagulation and accessories
Regulation number	21 CFR 878.4400	21 CFR 878.4400	21CFR 878.4400
Product code	PBX	PBX	PBX
FDA clearance	510(k) Cleared: K161458	510(k) Cleared: K162828	-
USE			

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ELEMENT OF COMPARISON	Primary Predicate Indiba Diathermia Radiofrequency Device (Indiba USA Inc.)	Reference predicate device Winback Back 3SE (Winback USA Corp)	Subject Device CAPENERGY - C100, C200, C300, C400, C50 (Capenergy Medical S.L)
Indications for use (from the Instructions for Use sheet)	The Indiba Diathermia Radiofrequency 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. The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.	The Winback Back 3SE device is 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 Winback Back 3SE massage device provided is intended to provide a temporary reduction in the appearance of cellulite.	The CAPENERGY C Devices - C100, C200, C300, C400, C50, 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

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ELEMENT OF COMPARISON	Primary Predicate Indiba Diathermia Radiofrequency Device (Indiba USA Inc.)	Reference predicate device Winback Back 3SE (Winback USA Corp)	Subject Device CAPENERGY - C100, C200, C300, C400, C50 (Capenergy Medical S.L)
Contraindications (from the Instructions for Use sheet)	Pacemakers or other electronical implants Pregnancy Skin disorders (open wounds or recent burnts) Thrombophlebitis External use. Do not use on endocavity ways (oral, vaginal, rectal) Persons suffering from lack of sensibility (congenital insensibility to pain, paraplegia or pharmacological treatments reducing sensibility to pain and heat)	The practitioner must avoid using the equipment on patients with: Pace maker Insulin pump Neurostimulators. Pregnancy High blood pressure or hypotension Cartilage growth Cancer Bleeding disorders Infectious diseases where heat is proscribed Phlebitis Tuberculosis. he practitioner must seek medical advice on the following: insensitivity to pain insensitivity to heat Burns Cancerous lesion in the treatment area.	Presence of pacemakers or other active implants, as cochlear implants, insuline pump, etc. Implanted cables Angina Epilepsy Nervous diseases Pregnancy Lactation Cardiovascular dysfunction Neoplasm Insensibility to temperature ,even if only temporary Decompensated arteriopathies Active infectious bacterial processes Coagulation problems Presence of metal implants (consult with specialist)
PRINCIPLE OF OPERATION			
Operating principle	Radio frequency diathermy	Radio frequency diathermy	Radio frequency diathermy
TECHNOLOGICAL CHARACTERISTICS			
General description	The Indiba Diathermia Radiofrequency Device is a therapeutic device for deep, non-invasive diathermy. The device consists of a console which generates a radiofrequency current which is delivered to the patient, in monopolar form, through two different types of electrodes: stainless steel conductive	The Winback Back 3SE 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 handheld electrode is	The CAPENERGY - C100, C200, C300, C400, C50 are devices for diathermy by energy transfer using radio frequency alternating electrical currents applied to the patient by using electrodes or plates. Its particular emission of frequencies, the ability to regulate and control the increase of the desired temperature allows to operate with a maximum

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ELEMENT OF COMPARISON	Primary Predicate Indiba Diathermia Radiofrequency Device (Indiba USA Inc.)	Reference predicate device Winback Back 3SE (Winback USA Corp)	Subject Device CAPENERGY - C100, C200, C300, C400, C50 (Capenergy Medical S.L)
	resistive electrodes, and thin-layer insulated capacitive electrodes. The electrodes are inserted into a handle/handpiece, one handle for each kind of electrode, and the handle is connected to the console by means of a 2-metre cable. In resistive mode the system delivers a high-frequency current of 448 kHz directly to the patient's skin surface. In capacitive mode, the electrode coating creates a layer between the electrode and the human tissue, forming a capacitor that allows a high-frequency current to pass.	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 and a multipolar 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 300 KHz to 1 MHz.	temperature of 45 °C, and never exceed 47 °C (for safety).
RF frequency	Frequency emission is limited to the following value: 0,40 MHz – 0,449 MHz	300kHz – 1 MHz	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%
Supply voltage and frequency	(100 – 240) V ~ 50/60 Hz	(100 – 240) V ~ 50/60 Hz	100–120/200–240V ± 10%, 50/60 Hz
Output power	100-200 W	300 W	45 W +/-10% for a charge of 06-j530 ohms to 1 MHz

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ELEMENT OF COMPARISON	Primary Predicate Indiba Diathermia Radiofrequency Device (Indiba USA Inc.)	Reference predicate device Winback Back 3SE (Winback USA Corp)	Subject Device CAPENERGY - C100, C200, C300, C400, C50 (Capenergy Medical S.L)
Dimensions	400 mm x 530 mm x 150 mm	1000 x 370 x 450 mm	562 mm x 211 mm x 420 mm 220 mm x 211 mm x 420 mm
Weight	8,6 kg (CT9); 8,4 kg (CT8)	18 Kg	10,7 Kg – 22,5 kg
Safety Class / Protection	Class I – Type BF	Class I – Type BF	Class I – Type BF
Waveform	Sinusoidal	Sinusoidal	Sinusoidal
Compliance with voluntary standards / LAB tests performed	IEC 60601-1:2005 IEC 60601-1-2:2007 IEC 62304:2006 ISO10993-1:2009	IEC 60601-1:2005 IEC 60601-1-2:2007 ISO10993-1:2009	IEC 60601-1:2005 + /A1:2012 IEC 60601-1-2:2015 IEC 60601-1-6:2010 IEC 62304:2006 ISO10993-1:2009
Environmental Conditions (Use)	Temperature: 10° to 40°C Relative Humidity: 30–75%	Temperature: 15° to 40°C Relative Humidity: 30–60%	Temperature: 10° to 40°C (+/- 20C) Relative humidity: less than 80%.

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SECTION 05 - 510(k) Summary

INTENDED USE:
As established in the Indications for Use Statement:

> 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 intended to provide a temporary reduction in the appearance of cellulite.

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.

SUMMARY DISCUSSION OF CLINICAL DATA:
Non-clinical test data are submitted to support this premarket notification and to establish substantial equivalence. No clinical studies are submitted.

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CONCLUSIONS:

The subject device CAPENERGY – C 100, C 200, C 300, C 400, C 50 – is similar to the predicate devices in principles of operation and technological characteristics. Testing was conducted to evaluate the performance of the subject device and to compare results to the performance of the predicate devices. Results of validation and verification activities in design control that included testing / certification to the designated standards and performance testing of the devices has demonstrated substantial equivalence of the subject device to the predicate in terms of safety and effectiveness for requested intended use.

We conclude that the subject device CAPENERGY - C 100, C 200, C 300, C 400, C 50 is substantially equivalent to the predicate devices in terms of safety and effectiveness for the requested intended use.