July 10, 2026

Capenergy Medical S.L.
Pilar Sanchez
General Manager
Av. Mare De Deu De Montserrat, 41 Bis Pje 1º Derecha
Sant Joan Despi, Barcelona 08970
Spain

Re: K253480
Trade/Device Name: Capenergy C Equipments RF C200 and C400 Drakarian
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: May 11, 2026
Received: May 27, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.07.10 14:46:10 -04'00'

For
Colin Kejing Chen, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253480

Device Name
Capenergy C Equipments RF C200 and C400 Drakarian

Indications for Use *(Describe)*
The Capenergy C Equipments RF C200 and C400 Drakarian are intended to provide topical heating for the purpose of elevating tissue temperature for dermatological procedures. The massage device is intended to provide a temporary reduction in the appearance of Cellulite. They are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

The Capenergy C Equipments RF C200 and C400 Drakarian are indicated for using for non-invasive reduction of abdominal circumference associated with subcutaneous fat induced by lipolytic processes.

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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SUBMISSION DATE: 07/10/2025
SENDER NAME: Capenergy Medical SL
PRESENTER'S ADDRESS: Av. Mare de Déu de Montserrat, 41 bis Pje 1º derecha
08970 Sant Joan Despí
Barcelona
Spain

CONTACT: Pilar Sánchez, General Director
TELEPHONE: +34 93 477 43 48
Email: pilar@capenergy.com

COMMERCIAL NAME OF THE DEVICE: Capenergy C Equipments RF C200 and C400 Drakarian
COMMON NAME: Massager, Vacuum, Radiofrequency-induced heat

DESCRIPTION OF THE REGULATIONS: General and Plastic Surgery
CLASS: Class II
REGULATION NUMBER: 21 CFR 878.4400
PRODUCT CODE: PBX, GEI

PREDICATE DEVICES
Primary predicate:
K192224 BTL-899 from BTL Industries, Inc.

Secondary Predicate(s):
K163415 Syneron Medical Ltd. SlimShape System
K222260 Capenergy C Equipment RF System C25, C50, C100, C200, C300, C400, C500 by Capenergy Medical SL

DEVICE DESCRIPTION:

The Capenergy C Drakarian RF C200 and C400 system, including its accessories, generates radiofrequency energy with temperature and impedance feedback for procedures requiring tissue heating. The Capenergy system constantly monitors the temperature and

impedance of the tissue being treated, automatically adjusting energy delivery to maintain effective and safe tissue heating.

The Capenergy C Drakarian RF C200 and C400 systems consist of an AC/DC power supply, an RF generator, a controller, and a user interface. The RF handpiece connects to the console via a cable, and a switch activates power management. The handpiece comprises internal and external electrodes.

INTENDED USE / INDICATIONS FOR USE:

The Capenergy C Equipments RF C200 and C400 Drakarian are intended to provide topical heating for the purpose of elevating tissue temperature for dermatological procedures. The massage device is intended to provide a temporary reduction in the appearance of Cellulite. They are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

The Capenergy C Equipments RF C200 and C400 Drakarian are indicated for using for non-invasive reduction of abdominal circumference associated with subcutaneous fat induced by lipolytic processes.

SUMMARY OF COMPARISON WITH THE PREDICATE DEVICE:

To establish substantial equivalence, Capenergy C Equipments' RF systems are compared to the following previously approved devices:

Primary predicate:

K192224 BTL-899 from BTL Industries, Inc.

Secondary Predicate:

K163415 SlimShape System from Syneron Medical Ltd.
K222260 Capenergy C Equipment RF System C25, C50, C100, C200, C300, C400, C500 by Capenergy Medical SL

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

	Subject Device	**Primary Predicate Device**	**First predicate of reference Device**	**Second predicate of reference Device**
Device name	Capenergy C RF C200 and C400 Drakarian equipment, includes Capenergy Non-Invasive Monopolar RF Reusable Electrode Set and Automatic Bipolar Belt	BTL-899	SlimShape System	The Capenergy C RF System devices - C25, C50, C100, C200, C300, C400, C500 include a set of Capenergy reusable non-invasive RF monopolar electrodes and automatic plates
Company Name	Capenergy Medical SL	BTL Industries, Inc.	Syneron Medical Ltd.	Capenergy Medical SL
Number 510(k)	Not Assigned	K192224	K163415	K222260
Regulation number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Product Code, Class	PBX, GEI, Class II	GEI, Class II	GEI, Class II	PBX, GEI, Class II
Instructions for use	The Capenergy C Equipments RF C200 and C400 Drakarian are intended to provide topical heating for the purpose of elevating tissue temperature for dermatological procedures. The massage device is intended to provide a temporary reduction in the appearance of Cellulite. They are indicated for use	BTL-899 is indicated for use in: • Non-invasive lipolysis (fat breakdown) of the abdomen. • Reduction of abdominal circumference - BTL-899 is designed for use with skin types I to III.	The SlimShape system is indicated for non-invasive lipolysis (fat breakdown) of the abdomen. The device is indicated for reducing abdominal circumference.	The Capenergy C RF System devices -C25, C50, C100, C200, C300, C400, C500- are designed to provide topical heating in order to raise tissue temperature for the treatment of selected medical conditions, such as: pain relief, muscle spasms, increased local circulation, and dermatological procedures.

	in dermatological and general surgical procedures for electrocoagulation and hemostasis. The Capenergy C Equipments RF C200 and C400 Drakarian are indicated for using for non-invasive reduction of abdominal circumference associated with subcutaneous fat induced by lipolytic processes.			The massage device is designed to provide a temporary reduction in the appearance of cellulite. The Capenergy C RF System equipment -C25, C50, C100, C200, C300, C400, C500- are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
Device Description	The Capenergy RF generator produces an oscillating electric field in the antenna (electrode). This field is transmitted to the surrounding soft tissue, causing it to heat up. A thermocouple in the electrode measures this temperature increase and maintains a feedback loop to ensure a reference temperature in the tissue. The system uses bipolar radio frequency.	The system combines bipolar radiofrequency with electromagnetic stimulation.	The system combines bipolar radiofrequency with mechanical suction.	The Capenergy RF generator produces an oscillating electric field in the antenna (electrode). This field is transmitted to the surrounding soft tissue, causing it to heat up. A thermocouple in the electrode measures this temperature increase and maintains a feedback loop to ensure a reference temperature in the tissue. The system uses monopolar radio frequency.

Clinical use	Prescription only	Prescription only	Prescription only	Prescription only
RF Power	Max. 180 W (45 W +/-10 per channel)	Max. 60 W (30 W per channel)	80 W (1 channel)	Max. 180 W (45 W +/-10 per channel)
Internal Cut	40-45ºC	40 –43°C	40 –43°C	40-45ºC
Treatment time	Up to 30 min	Up to 30 min	Up to 30 min	Up to 30 min
RF Frequency	Fixed values are set for treatment time, output power percentage, and operating frequency . Three options are available: 0.8 MHz +/-25%, 1.0 MHz +/-25%, and 1.2 MHz +/-25%.	27.12 MHz	1 MHz	Fixed values are set for treatment time, output power percentage, and operating frequency . Four options are available: 0.448 MHz +/-25%, 0.8 MHz +/-25%, 1.0 MHz +/-25%, and 1.2 MHz +/-25%.
RF type	Bipolar	Bipolar	Bipolar	Monopolar
Waveform	Sinusoidal	Sinusoidal	Sinusoidal	Sinusoidal
Safety class Protection	Class I – Type BF	Class II – Type BF	Class I – Type BF	Class I – Type BF
Use the interface	Screen and buttons	Touch screen	Touch screen	Screen and buttons
Supply voltage and frequency	100–120/200–240 V ± 10%, 50/60 Hz	100 – 240 V AC, 50–60 Hz	100 – 230 V AC, 50–60 Hz	100–120/200–240 V ± 10%, 50/60 Hz
Firmware controlled	Yes	Yes	Yes	Yes
Temperature sensor and control	Yes	Yes	Yes	Yes

Parameter selection (Intensity, Time)	Yes	Yes	Yes	Yes
Application	Automatic, manual, and hands-free applicators Automatic hands-free applicator, secured by a fastening belt.	Hands-free applicator, secured by a fastening belt.	Hands-free applicator, secured by a fastening belt.	Automatic, manual, and hands-free applicators
Impedance fabric	50-300 ohms	50-300 ohms	50-300 ohms	50-300 ohms
Dimensions (Width x Height x Depth)	170 x 220 mmx250 mm 345x 220 mmx420 mm 562 mmx 220 mmx420 mm	23 x 39 x29 in (592 x 985 x 730 mm)	19.6 x 40.7 x20.7 in	170 x 220 mmx 250 mm345 420 mmxx220 mm 562 mmx 420 mmx220 mm
Weight	13 -26.5 Kg	85 Kg	53 Kg	13 -26.5 Kg
Compliance with voluntary standards / laboratory 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 ISO10993-5 ISO10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC ISO10993-1:2009 ISO10993-5 ISO10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC ISO10993-1:2009 ISO10993-5 ISO10993-10	IEC 60601-1:2005 + /A1:2012 I CE 60601-1-2:2015 IEC 60601-1-6:2010 IEC 60601-2-2:2017 IEC 62304:2006 ISO10993-1:2009 ISO10993-5 ISO10993-10
Environmental conditions	Temperature: 10° to 40°C(+/- 20C) Relative humidity: less than 80%. For indoor use only Unsafe RM	Temperature: 10° to30°C Relative humidity: 30% to 75%. For indoor use only Unsafe RM	Temperature: 10° to30°C Relative humidity: 30% to 80%. For indoor use only Unsafe RM	Temperature: 10° to 40°C(+/- 20C) Relative humidity: less than 80%. For indoor use only Unsafe RM

SUMMARY DISCUSSION OF NONCLINICAL TESTS (21 CFR 807.92(b)(1))

Preclinical functional tests were performed to evaluate the safety and performance of the Capenergy C RF C200 and C400 Drakarian devices in relation to their intended use and to address potential risks associated with radiofrequency tissue heating. ***and*** The patient contact materials were tested. Testing included verifying the device's ability to reach and maintain therapeutic tissue temperatures (40-45 °C) during treatments of up to 30 minutes under foreseeable operating conditions, as well as its efficacy in treatments. These tests were performed using the C200 device in 2019, which is equivalent to the C200 Drakarian, as it uses the same active and passive plates, the same as those that make up the CBelt belt, and the same temperature control, common to the entire Capenergy (K222260) device family.

Additional non-clinical testing addressed electrical safety and electromagnetic compatibility in accordance with IEC 60601-1 and IEC 60601-1-2 and confirmed that the device meets applicable safety and EMC requirements.

The software verification and validation were performed in accordance with IEC 62304 and the FDA software validation guide, demonstrating that the software functions reliably and as intended.

Materials in contact with the patient were evaluated in accordance with ISO 10993-1, including applicable biocompatibility endpoints, and were determined to be biocompatible for the intended duration and type of contact.

The results of these non-clinical tests demonstrate that the device in question works as intended and is as safe and effective as the identified precursor devices.

Although the device in question, Drakarian, has a higher maximum output power than the original device, the integrated temperature monitoring and automatic power adjustment ensure that tissue temperatures remain within the same therapeutic range as the original devices.

In addition to electrical safety testing, the software was verified and validated according to IEC 62304:2006 (Software for Medical Devices), Software Lifecycle Processes, and FDA guidelines on software validation. The results of these tests conclude that the software meets these requirements.

The materials in contact with the patient have been evaluated in accordance with the requirements of ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing, and were confirmed to be biocompatible for the intended use.

The results of these non-clinical tests demonstrate that the device in question works as intended and is as safe and effective as the original devices.

SUMMARY DISCUSSION OF CLINICAL TRIALS (21 CFR 807.92(b)(2))

The conducted clinical study was a single-center, prospective cohort, a paired case-control study where each individual served as their own control.

Objectives:
Primary Objectives

- Demonstrate the effectiveness in reducing abdominal circumference and subcutaneous fat in 12 weeks after treatments with the Capenergy bipolar radiofrequency belt.
- Demonstrate the safety of treatment with the Capenergy bipolar radiofrequency belt.

Secondary Objectives

- Evaluate the efficacy in reducing abdominal circumference at all visits (starting from visit 2).
- Evaluate the effectiveness in reducing abdominal fat at all visits (starting from visit 3).
- Evaluate the level of comfort during treatments, at all visits (starting with visit 2), reported by patients.
- Evaluate the satisfaction reported by the subjects, and the improvement reported by the researcher

Endpoints:
Primary Efficacy Endpoints

- Statistically significant reduction in abdominal circumference after Drakarian device treatments at 12 weeks of follow-up versus baseline.
- Statistically significant reduction in subcutaneous fat after Drakarian equipment treatments at 12 weeks of follow-up versus baseline.

Secondary Efficacy Endpoints

- Statistically significant reduction in abdominal circumference after treatment with Drakarian equipment at each visit (beginning with the second treatment) compared to baseline, as measured by tape measures and a caliper.

- Statistically significant reduction in abdominal fat after treatment with Drakarian equipment at each visit (beginning with the third treatment) compared to baseline, using ultrasound imaging measurements.
- Patient self-assessment for satisfaction and improvement using questionnaires at each visit (starting with the second treatment).
- Patient discomfort (pain) level after each treatment (Tx.1, Tx.2 and Tx.3), using a 10-point visual analog scale (Numeric Scale Response (NSR)).

Primary Safety End Point

- The number, severity, and type of any adverse events recorded throughout the study.
- Immediate response in each treatment (Tx.1, Tx.2 & Tx.3).

The results showed improvement and the AEs are consistent with known events.

SUMMARY OF THE DISCUSSION ON SUBSTANTIAL EQUIVALENCE.

Based on technological comparison to the predicate devices and performance testing, the Capenergy C RF C200 and C400 Drakarian devices with their Capenergy reusable non-invasive RF monopolar electrode set and their CBelt bipolar belt , are substantially equivalent in terms of safety and effectiveness for the requested indications for use.