February 5, 2025

Creo Medical Ltd
Diane Davis
RAQA Product Lead
Unit 2 Beaufort Park
Beaufort Park Way
Chepstow, NP16 5UH
United Kingdom

Re: K242983
Trade/Device Name: CROMA Electrosurgical Generator (PRD-EMR-050)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, NEY, KNS
Dated: January 6, 2025
Received: January 6, 2025

Dear Diane Davis:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2025.02.05 13:05:38 -05'00'

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)*
K242983

Device Name
CROMA Electrosurgical Generator (PRD-EMR-050)

Indications for Use *(Describe)*
The CROMA Electrosurgical Generator is intended to provide Radiofrequency (RF) and microwave (MW) energy for cutting, coagulation, and ablation of soft tissue, when used in conjunction with compatible electrosurgical instruments and accessories.
The Creo Medical Electrosurgical System is not intended for use in cardiac procedures.

The Reusable Interface Cable is for connection only of a compatible Creo Medical Instrument (Surgical Accessory) to the CROMA Electrosurgical Generator to deliver Radiofrequency (RF) and/or Microwave (MW) energy for the cutting, coagulation and ablation of tissue via endoscopic access.

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.

K242983 510(k) Summary

CROMA Electrosurgical Generator

Date Prepared: February 4, 2025

CONTACT DETAILS

Applicant Name:	Creo Medical Ltd.
Applicant Address:	Unit 2 Beaufort Park, Beaufort Park Way, Chepstow NP16 5UH, UK
Applicant Contact Telephone:	+44 7899 306000
Applicant Contact:	Diane Davis
Applicant Contact Email:	diane.davis@creomedical.com

DEVICE NAME

Device Trade Name	CROMA Electrosurgical Generator (PRD-EMR-050)
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Product Code(s)	GEI, NEY, KNS

LEGALLY MARKETED PREDICATE DEVICES

K230328	Speedboat Flush SB1 Instrument with Croma Electrosurgical Generator, Product Code KNS
K223138	AB1 Electrosurgical Instrument, Creo Electrosurgical System, Product Code NEY

DEVICE DESCRIPTION SUMMARY

The CROMA Electrosurgical Generator is an Electrosurgical unit (ESU) to be used with compatible electrosurgical instruments and accessories.

The CROMA Electrosurgical Generator is a tabletop, non-network connected, mains powered ESU. It comprises two distinct energy sources for the independent generation of bipolar radiofrequency (RF) and microwave (MW) energies, intended to supply electrosurgical power for cutting, coagulation, and ablation of soft tissues, when connected to compatible instruments via the interface cable.

The CROMA Electrosurgical Generator incorporates proprietary software developed by Creo Medical Ltd.

The CROMA Electrosurgical Generator subject of this submission incorporates a new front panel, which has been updated from a Vacuum Fluorescent Display (VFD) in the predicate device to a Liquid Crystal Display (LCD) screen in the subject device.

The subject and predicate devices have identical principles of operations:

- Supply suitable Creo Medical instruments with appropriate power for their surgical uses at a MW frequency of 5.8 GHz for the purpose of coagulation, cauterisation and/or ablation.
- Supply suitable Creo Medical instruments with appropriate power for their surgical uses at a nominal RF of 400 kHz for the purpose of cutting.

INDICATIONS FOR USE STATEMENT

The CROMA Electrosurgical Generator is intended to provide Radiofrequency (RF) and microwave (MW) energy for cutting, coagulation, and ablation of soft tissue, when used in conjunction with compatible electrosurgical instruments and accessories.

The Creo Medical Electrosurgical System is not intended for use in cardiac procedures.

The Reusable Interface Cable is for connection only of a compatible Creo Medical Instrument (Surgical Accessory) to the CROMA Electrosurgical Generator to deliver Radiofrequency (RF) and/or Microwave (MW) energy for the cutting, coagulation and ablation of tissue via endoscopic access.

INDICATIONS FOR USE COMPARISON

The subject device has the same Indications for Use as the predicate devices. The indications for use statement for the subject device has been reworded for readability and clarity by removing the redundancy and the specific reference of the compatible instruments. Instead, compatible instruments are provided in a table form in the Instructions for Use, right under the Intended Use Statement.

Therefore, this formatting change does not raise concerns of safety and effectiveness.

TECHNOLOGICAL COMPARISON

The subject and predicate devices have the following same technological characteristics:

- Energy inputs
- Energy outputs
- Principles of operations
- Functionalities of the control console (front panel), including push buttons, output sockets for interface cable connection, symbols, LED lights and audio tones in compliance with IEC 60601 requirements.

The subject device has been modified to modernise the visual of the user interface and upgrade the screen from a Vacuum Fluorescent Display (VFD) to a Liquid Crystal Display (LCD). As a result, the following technological differences exist between the subject and predicate devices:

- Front panel screen changed from VFD to LCD
- Front panel keypad membrane updated (aesthetics, features location)
- Software changed to support the new LCD screen, as well as include other minor software updates

The differences in the subject device technological characteristics do not raise concerns of safety and effectiveness.

Characteristic	**Subject** **CROMA Electrosurgical Generator PRD-EMR-050**	**Primary Predicate** **CROMA Electrosurgical Generator 7-EMR-050 (K230328)**	**Secondary Predicate** **CROMA Electrosurgical Generator 7-EMR-050 (K223138)**
Classification:	Class II	SAME	SAME
Regulation:	21 CFR 878.4400	21 CFR 876.4300	SAME
Product Code:	GEI – Electrosurgical, Cutting & Coagulation & Accessories	KNS – Unit, Electrosurgical, Endoscopic	NEY – System, Ablation, Microwave And Accessories
Intended Use / Indications For Use CROMA Electrosurgical Generator:	The CROMA Electrosurgical Generator is intended to provide Radiofrequency (RF) and Microwave (MW) energy for cutting, coagulation, and ablation of soft tissue, when used in conjunction with compatible electrosurgical instruments and accessories.	The Electrosurgical Generator provides microwave (MW) energy to compatible Creo Medical instruments AB1 MicroBlate Flex and NP1 MicroBlate Fine instruments, intended for coagulation (ablation) of soft tissue. The Electrosurgical Generator provides microwave (MW) energy to compatible Creo Medical instruments HS1 SlypSeal	The Electrosurgical Generator provides microwave (MW) energy to compatible Creo Medical instruments AB1 MicroBlate Flex and NP1 MicroBlate Fine instruments, intended for coagulation (ablation) of soft tissue. The Electrosurgical Generator provides microwave (MW) energy to compatible Creo Medical instruments HS1 SlypSeal

Characteristic	Subject **CROMA Electrosurgical Generator PRD-EMR-050**	Primary Predicate **CROMA Electrosurgical Generator 7-EMR-050 (K230328)**	Secondary Predicate **CROMA Electrosurgical Generator 7-EMR-050 (K223138)**
	The Creo Medical Electrosurgical System is not intended for use in cardiac procedures.	Instrument, intended for coagulation (hemostasis and cauterization) of soft tissue. The Electrosurgical Generator provides microwave (MW) and radiofrequency (RF) energy to compatible Creo Medical Speedboat Instruments, intended for coagulation (hemostasis and cauterization) and cutting soft tissue. The Electrosurgical System is not intended for use in cardiac procedures.	Instrument, intended for coagulation (hemostasis and cauterization) of soft tissue. The Electrosurgical Generator provides microwave (MW) and radiofrequency (RF) energy to compatible Creo Medical Speedboat Instruments, intended for coagulation (hemostasis and cauterization) and cutting soft tissue. The Electrosurgical System is not intended for use in cardiac procedures.
Display:	Liquid Crystal display (LCD) supporting Alphanumeric, Chinese and Japanese characters.	Vacuum fluorescent display (VFD) supporting Alphanumeric characters.	Vacuum fluorescent display (VFD) supporting Alphanumeric characters.
Mains power input:	Input Voltage: 100 V – 120 V / 220 V – 240 V. Maximum Input Power: 450 W. Frequency: 50 / 60 Hz, Single phase.	SAME	SAME
Protective class (IEC 60601-1):	Equipment is Class I Requires a protective ground connection.	SAME	SAME
Patient circuit, as per IEC 60601-1:	Type CF	SAME	SAME
Degree of IP protection:	IP00	SAME	SAME
Energy output:	RF output: 400 Hz MW output: 5.8 GHz	SAME	SAME
Maximum voltage:	RF: 460 Vpeak MW: 79 Vpeak (50 Ohm load)	SAME	SAME
RF output modality:	Bipolar, single waveform	SAME	SAME
RF output operating frequency:	396.7 kHz ± 2.0 kHz	SAME	SAME

Characteristic	Subject CROMA Electrosurgical Generator PRD-EMR-050	Primary Predicate CROMA Electrosurgical Generator 7-EMR-050 (K230328)	Secondary Predicate CROMA Electrosurgical Generator 7-EMR-050 (K223138)
RF output capability (Biomed mode):	200 W maximum into a rated load of 400 Ohm	SAME	SAME
RF output capability (treatment mode):	35 W (Max) into a rated load of 400 Ohm	SAME	SAME
RF output adjustment:	15 W to 35 W at the rated load of 400 Ohm. 10 s ON, 30 s OFF, 1 hour	SAME	SAME
MW output modality:	Microwave, single waveform.	SAME	SAME
MW output operating frequency:	5.8 GHz ± 1 MHz	SAME	SAME
MW output capability (treatment mode):	62 W maximum into a rated load of 50 Ohm	SAME	SAME
MW output power:	AB1 – 27 W (for use with Interface Cable 2m only) NP1 – 62 W	AB1 – 25W NP1 – SAME	AB1 – 25W NP1 – SAME
MW output duration:	Defined in the generator IFU: RS2 – 10 s ON, 1 s OFF x 3, then 268 s OFF HS1 – 10 s ON, 1 s OFF x 5, then 246 s OFF SB1-L – 5 s ON, 1 s OFF x 5, then 268 s OFF AB1 – 180 s ON, 30 s OFF x 9, then 28 min 30 sec OFF NP1 – 120 s ON, 30 s OFF x 8, then 40 min OFF	Defined in the generator IFU: RS2 – SAME HS1 – SAME SB1-L – SAME AB1 – SAME NP1 – 120 s ON, 120 s OFF x 8, then 28 min OFF	Defined in the generator IFU: RS2 – SAME HS1 – SAME SB1-L – SAME AB1 – SAME NP1 – 120 s ON, 120 s OFF x 8, then 28 min OFF

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted on the subject device as part of the Creo Medical Electrosurgical System. The system complies with IEC 60601-1 Ed. 3.2, IEC 60601-2-2 Ed. 6.0, IEC 60601-2-6 Ed. 2.1, and IEC 60601-1-2:2014.

Software verification and validation testing

The software for this device was developed, verified and validated in with IEC 62304 Ed. 1.1. The software for this device requires an enhanced documentation level, as a failure or flaw of the software could present a hazardous situation with a probable risk of death or serious injury to the patient or user of the device.

Mechanical and Usability testing

At a high level, the following mechanical and usability testing have been performed on the subject device:

- Device power on/off, initialisation, standby, timeout testing
- Settings, language, and accessory selection testing
- Accessory connection / reconnection testing
- Usability assessment of the changes to the user interface

Animal & Clinical Studies

Not Applicable.

CONCLUSION

Technological differences between subject and predicate devices do not raise new questions of safety or effectiveness. Based on the comparison of the indications for use, technological characteristics, and performance test results to the same of the predicate predicate, the subject CROMA Electrosurgical Generator has been shown to be substantially equivalent to the predicate devices for the requested indications for use.