August 15, 2024

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

Re: K242061
Trade/Device Name: Reusable Interface Cable 1.5 m (PRD-IFC-002)
Regulation Number: 21 CFR 876.4300
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: July 15, 2024
Received: July 15, 2024

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.

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology 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.*

Submission Number *(if known)*

K242061

Device Name

Reusable Interface Cable 1.5 m (PRD-IFC-002)

Indications for Use *(Describe)*

The 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 energy for the cutting, coagulation and ablation of gastrointestinal tissue.

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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510(k) #: K242061

# 510(k) Summary

Prepared on: 2024-08-01

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Creo Medical Ltd |
| Applicant Address | Unit 2 Beaufort Park Beaufort Park Way Chepstow NP16 5UH United Kingdom |
| Applicant Contact Telephone | +44 7899306000 |
| Applicant Contact | Dr. Diane Davis |
| Applicant Contact Email | diane.davis@creomedical.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Reusable Interface Cable 1.5 m (PRD-IFC-002) |
| Common Name | Endoscopic electrosurgical unit and accessories |
| Classification Name | Unit, Electrosurgical, Endoscopic (With Or Without Accessories) |
| Regulation Number | 876.4300 |
| Product Code(s) | KNS |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K230328 | Speedboat Flush SB1 Instrument, Creo Electrosurgical System | KNS |

## Device Description Summary

21 CFR 807.92(a)(4)

The Reusable Interface Cable comprises a flexible, low-loss coaxial cable intended for high-power microwave operation and has latching connectors at each end for connection to the CROMA Electrosurgical Generator and compatible Creo Medical Instruments (Surgical Accessories). The established lifetime of the Reusable Interface Cable is for 20 uses in total.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The 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 energy for the cutting, coagulation and ablation of gastrointestinal tissue.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same Indications for Use as the predicate device. The indications for use for the subject device has been reworded for readability.

## Technological Comparison

21 CFR 807.92(a)(6)

The Interface Cable has push-fit latching connectors on each end designed to deliver energy at both Radiofrequency and Microwave frequencies between the CROMA Electrosurgical Generator and the compatible instrument.

The subject device is a reusable version of the predicate device. To improve durability for reuse over the established lifetime, the conductor cable of the subject device has been modified while maintaining identical electrical properties.

The subject and predicate devices have identical principles of operations, electrical properties, energy source, materials, dimensions and cleaning method.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Electrical safety testing was conducted on the subject device in compliance with FDA-recognized versions of IEC 60601-1, IEC 60601-2-2 and IEC 60601-2-6 standards.

Performance bench testing was conducted to establish device durability over the established lifetime for:
- cleaning between uses (reprocessing)
- rotation load
- cyclic load
- connectors connection and disconnection forces.