June 6, 2025

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

Re: K242774
Trade/Device Name: SpydrBlade Flex Instrument (PRD-RG1-001)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: May 9, 2025
Received: May 9, 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,

SIVAKAMI VENKATACHALAM -S

for
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)*

K242774

Device Name

SpydrBlade Flex Instrument (PRD-RG1-001)

Indications for Use *(Describe)*

The SypdrBlade Flex Instrument is indicated for use in the cutting (incision, dissection, avulsion) of soft tissue using radiofrequency energy and the coagulation (hemostasis, cauterization, arrest of bleeding) of soft tissue using microwave energy in the gastrointestinal tract as required or encountered in endoscopic procedures.

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.

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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510(k) #: K242774

510(k) Summary

Prepared on: 2025-05-09

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
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	SpydrBlade Flex Instrument (PRD-RG1-001)
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	KNS

Device Description Summary

21 CFR 807.92(a)(4)

The Creo Medical electrosurgical system comprises of the CROMA electrosurgical generator, an interface cable accessory and a footswitch accessory, and a compatible electrosurgical instrument.

The CROMA electrosurgical generator comprises two distinct energy sources for the independent generation of bipolar radiofrequency (RF) current at 400 kHz and microwave (MW) current at 5.8 GHz.
Both energy sources are delivered through the same output coaxial connector. These generator outputs are controlled in terms of voltage, power, current, duty cycle, and duration by means of widely used and long-established design and engineering techniques. Via these controls and system design, only one energy source can be delivered to the output coaxial connector at any one time.

The compatible electrosurgical instrument that is subject of this submission is SpydrBlade Flex. The subject and predicate devices use the same electrosurgical generator, footswitch, and interface cable.

SpydrBlade Flex is a single-use, sterile endoscopic electrosurgical instrument used for procedures in the gastrointestinal (GI) tract. The product is sterilized using Ethylene Oxide.
SpydrBlade Flex is intended for use in endoscopes with a minimum working channel of 3.2 mm and maximum working length of 1.35 m.

SpydrBlade Flex incorporates a distal tip, a shaft, and a handle. The distal tip includes a jaws assembly that consists of two gold-plated ceramic bipolar antennas, each soldered to a stainless-steel base. The stainless-steel bases are joined in a manner to provide a mechanical opening and closing function. The bipolar antennas deliver RF energy for cutting and MW energy for coagulation, in the same manner as the predicate Speedboat SB1. The cutting and coagulation functions are performed regardless of the jaw mechanism and can be provided with the jaws open or closed. The jaw mechanism provides a grasping function for easier tissue manipulation between and during energy applications.

The subject and predicate devices are composed of the same technological components with the same principles of operation related to the energy function:
• Cutting of mucosa, sub-mucosa, muscle using bipolar RF energy,
• Thermal coagulation of mucosa and/or sub-mucosa, muscle, vascular and arterial structures using MW energy.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The SypdrBlade Flex Instrument is indicated for use in the cutting (incision, dissection, avulsion) of soft tissue using radiofrequency energy and the coagulation (hemostasis, cauterization, arrest of bleeding) of soft tissue using microwave energy in the gastrointestinal tract as required or encountered in endoscopic procedures.

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indication for use of the subject device is the same as the predicate device with regards to the essential endoscopic functions.
The subject device does not incoroporate the fluid injection feature of the predicate device. However, a fluid injection function is a convenience tool which is otherwise available and frequently provided by a standalone injection tool. Therefore, the difference does not constitute a new intended use.

Technological Comparison 21 CFR 807.92(a)(6)

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

DESIGN:
Both subject and predicate devices are composed of a handle, a shaft, and a distal tip. The handle acts as the proximal end for the user and electrical connection to the CROMA electrosurgical generator. The shaft connects the handle to the distal tip, and the distal tip acts as the distal end for energy delivery to the patient.
Both devices' distal tips act as the distal end for RF and MW energy delivery to the patient. The RF and MW energy delivery of the subject device is the same as the predicate device. The RF and MW energy delivery is independent of the jaw design, and only depends on the design of the bipolar antenna. The bipolar antennas of the subject device have similar dimensions and technological characteristics as the bipolar antenna of the predicate device, and the differences do not impact RF and MW energy delivery.

MATERIALS:
The subject device is composed of the same materials as the predicate device, with the exception of one material with direct patient contact. Biological evaluation indicated that the new material did not raise new biocompatibility concerns for the subject device.

PRINCIPLES OF OPERATION:
The subject and predicate have identical cutting and coagulation functions:
• Cutting of mucosa, sub-mucosa, muscle using bipolar RF energy,
• Thermal coagulation of mucosa and/or sub-mucosa, muscle, vascular and arterial structures using MW energy.
The predicate device has a fluid injection function which is not applicable to the subject device and not critical to the intended use of the device.

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

Sterilization and Shelf-life:
As per ISO 11135:2014 and AAMI TIR28:2016 standard evaluation, SpydrBlade Flex sterility assurance level is 10^-6. The shelf-life for the SpydrBlade Flex instrument is 1 year (12 months).

Biocompatibility:
The biological evaluation of SpydrBlade Flex was conducted in accordance with ISO 10993-1:2009 and the FDA guidance document, Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process: Guidance for Industry and Food and Drug Administration Staff," issued by the FDA on June 16, 2016.
The biological risk assessment performed provide evidence that SpydrBlade Flex meets all required biological endpoints.

Electrical Safety, Microwave Safety and Electromagnetic Compatibility:
Electrical safety and EMC testing complies with IEC 60601-1, IEC 60601-2-2 and IEC 60601-2-6, IEC 60601-2-18 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation:
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Performance testing via bench tests:
All required design verification and validation bench testing were performed, all bench tests passed the acceptance criteria.
The performance bench testing indicated that SpydrBlade Flex is substantially equivalent to the predicate device.

Clinical Testing: Not Applicable.

All required nonclinical testing were performed and passed the acceptance criteria.
The results indicate that SpydrBlade Flex is substantially equivalent to the predicate device, and that SpydrBlade Flex does not raise concerns of safety and effectiveness.