October 31, 2023

Creo Medical Ltd
Diane Davis
Regulatory Specialist
Unit 2 Beaufort Park, Beaufort Part Way
Chepstow, Monmouthshire NP16 5UH
United Kingdom

Re: K230328
Trade/Device Name: Speedboat Flush SB1 Instrument
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: September 29, 2023
Received: September 29, 2023

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230328

Device Name
Speedboat Flush SB1 Instrument

Indications for Use *(Describe)*
Intended for use in the cutting of soft tissue using radiofrequency current, the coagulation (hemostasis, cauterization) of soft tissue using microwave energy, and the delivery and injection of solutions for endoscopic surgical procedures within the gastrointestinal tract.

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.

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510(k) Summary

Speedboat Flush SB1 Instrument

SUBMITTER INFORMATION

Company Name: Creo Medical Ltd.

Company Address: Unit 2 Beaufort Park, Beaufort Park Way, Chepstow NP16 5UH, UK

CONTACT

Name: Diane Davis

Telephone: +44 7899 306000

Email: diane.davis@creomedical.com

Date Prepared: February 6rd, 2023.

DEVICE IDENTIFICATION

Trade Name: Speedboat Flush SB1 Instrument

Common Name: Electrosurgical system with surgical instrument

Classification Name: Endoscopic electrosurgical unit and accessories

Regulation Number: 21 CFR 876.4300

Product Code: KNS

Regulatory Class: Class II

PREDICATE DEVICE INFORMATION

K171983 Creo Medical Electrosurgical System including Speedboat RS2 Surgical Accessory

SYSTEM DESCRIPTION

The Creo Medical Electrosurgical System with Speedboat surgical instrument comprises:

- Electrosurgical Generator (7-EMR-050)
- Footswitch (2-EMR-032)
- Interface Cable Procedure Pack (cable with sterile sheath) (7-RS2-210)
- Speedboat RS2 instrument (7-RS2-001)
- Speedboat RS2 8 Fr instrument (7-RS2-003)
- Speedboat SB1 instrument (7-RS2-001)

The Electrosurgical Generator is designed to deliver bipolar radiofrequency (RF) energy and microwave energy for the purpose of cutting and coagulating tissue. The Electrosurgical Generator output is actuated via a two-pedal Footswitch. One pedal activates the bipolar RF energy output for cut; the other pedal activates the microwave energy output for coagulation. The Electrosurgical Generator incorporates proprietary software developed by Creo Medical for generating and controlling the two energies delivered. The Electrosurgical Generator and Footswitch are non-sterile and reusable.

The Interface Cable connects electrosurgical instruments to the Electrosurgical Generator and is for single-use and is supplied with a sterile sheath that is fitted over its distal end during connection to the surgical accessory.

Speedboat is an electrosurgical instrument for use with the Creo Medical Electrosurgical Generator only. Speedboat instrument is for endoscopic use and provides cutting, coagulation and injection of fluids incorporated in a single device. Speedboat Instrument is for single-use only and is provided sterile via EO sterilization.

Speedboat SB1 instrument is a line addition to the system, designed to be used in endoscopes with a minimum working channel of 2.8 mm.

INDICATIONS FOR USE STATEMENT

Intended for use in the cutting of soft tissue using radiofrequency current, the coagulation (hemostasis, cauterization) of soft tissue using microwave energy, and the delivery and injection of solutions for endoscopic surgical procedures within the gastrointestinal tract.

TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS

The Electrosurgical Generator comprises two distinct energy sources for the independent generation of bipolar radiofrequency (RF) current at 400 kHz and microwave 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.

Speedboat SB1 instrument is 2.3 m long and used through the working channel of a compatible endoscope. The distal tip comprises:

- a gold-metallized ceramic bipolar electrode assembly (Antenna) for delivery of cutting and coagulation energies;
- a stainless-steel rounded contour component (Hull) mounted to the Antenna;
- a fluid lumen for delivery and injection of fluids.

The proximal handle of Speedboat SB1 incorporates a luer-lock port for connection of a user-supplied syringe containing injection solution and a coaxial connector for connection to the Interface Cable.

The Interface Cable has push-fit latching connectors on each end designed to deliver energy at both RF and microwave frequencies.

The subject and predicate devices use the same electrosurgical generator, footswitch, and interface cable. They are composed of the same technological components with the same principles of operation which are:

- Cutting of mucosa, sub-mucosa, muscle using bipolar RF energy,
- Thermal coagulation (cauterization) of mucosa and/or sub-mucosa, muscle, vascular and arterial structures using microwave energy,
- Injection of a fluid into the sub-mucosa using the fluid injection function located at the distal tip of the device.

COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following technological differences between the subject and predicate device were compared:

Difference	Equivalence assessment
Fluid injection function The subject device incorporates a fluid lumen while the predicate incorporates an extendable and retractable needle for fluid injection.	The subject device was tested to be able to produce a jet (constant stream) of saline from the device tip at minimum pressure which has been determined to be equivalent to the use of a needle for the intended device operation.
Shaft diameter outer shaft diameter is 2.35 mm compared to 3.2 mm for predicate Speedboat RS2. It is to be compatible with an endoscope of minimum working channel 2.8 mm instead of minimum 3.7 mm.	The subject device performances were evaluated via the bench tests listed below and has been determined to be substantially equivalent to the predicate device.
Distal tip dimensions The antenna of the subject device is slightly longer and thinner compared to the predicate device. However, the shape of the antenna and distance between the electrode has not changed.	The subject device lifetime cut and coagulation performance was evaluated and demonstrated to be substantially equivalent to the predicate device.
Handle design The handle of the subject device has had an overall redesign compared to the predicate device. As the device does not incorporate a needle, the slider to actuate the needle has been removed.	The function of the handle has not changed and incorporate the same connections for RF and microwave energy output (QMA connector) and for fluid injection (luer lock connector). The handle was evaluated via the bench tests listed below and has been determined to be substantially equivalent to the predicate device.

The system meets all design specifications, risk mitigation requirements and applicable medical device standard requirements.

PERFORMANCE DATA

Sterilization and Shelf-life

As per ISO 11135:2014 and AAMI TIR28:2016 standard evaluation, Speedboat SB1 sterility assurance level is 10^{-6}.

The shelf-life for the Speedboat SB1 instrument is 1 year (12 months).

Biocompatibility

The biocompatibility evaluation of Speedboat SB1 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.

When used as intended, Speedboat SB1 Instrument is categorized as an externally communicating device in limited contact (≤ 24 hours) with tissue. Following Speedboat SB1 categorization as per Attachment A of the FDA guidance and Table A.1 Annex A of ISO 10993-1, the relevant biological endpoints are:

- Physical and/or chemical information
- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Material-mediated pyrogenicity
- Acute systemic toxicity
- Hemocompatibility via hemolysis

the biological risk assessment performed provide evidence that Speedboat SB1 meets all required biological endpoints.

Electrical Safety, Microwave Safety and Electromagnetic Compatibility

Electrical safety and EMC tests were conducted on the Creo Medical Electrosurgical System with Speedboat Instrument. The system complies with FDA-recognized versions of IEC 60601-1, IEC 60601-2-2 and IEC 60601-2-6 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

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

The following bench tests were performed:

- Lifetime Cut & coagulation;
- Connection latch and retention;
- Minimum bend radius;
- Connector rotation;
- Fluid injection;
- Device rotation;
- Device & injection fluid temperature;
- Endoscope insertion and withdrawals;
- Vector Network Analysis (VNA);
- Hot tissue damage;
- Cutting speed and thermal margin;
- Distal tip shear force;
- Components and sub-assemblies strength.

All bench tests passed the acceptance criteria and indicated that Speedboat SB1 is substantially equivalent to the predicate device.

CONCLUSION

Based on the indications for use, technological characteristics, performance results, and comparison to the predicate, the Speedboat Flush SB1 has been shown to be substantially equivalent to the predicate device identified in this submission and does not present any new issues of safety or effectiveness.