March 19, 2020

Creo Medical Ltd.
% Leif Geoghegan
Senior Design and Development Engineer
Phil Triolo and Associates LC
Creo House, Unit 2, Beaufort Park Way
Chepstow, NP16 5 UH
United Kingdom

Re: K192905
Trade/Device Name: Creo Electrosurgical System with HS1 Hemostasis Accessory
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: February 18, 2020
Received: February 19, 2020

Dear Leif Geoghegan:

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 (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 located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

for
Shani P. Haugen, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192905

Device Name
Creo Electrosurgical System with HS1 Hemostasis Accessory

Indications for Use *(Describe)*
The Creo Electrosurgical Generator is intended to provide radiofrequency (RF) electrosurgical energy for cutting and microwave energy (MW) for coagulation (hemostasis, cauterization) of soft tissue, and is for use only with compatible Creo Medical instruments and accessories.

The HS1 Hemostasis Accessory is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following:

- Peptic Ulcers
- Dieulafoy Lesions
- Mallory-Weiss Tears
- Bleeding Polyp Stalks
- Arteriovenous Malformations (AVMs)
- Angiomata

The HS1 also has irrigation capability. Any other use is not recommended.

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

Date Prepared: October 11, 2019

1.GENERAL

510(k) Sponsor: Creo Medical Ltd
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Contact Person: Leif Geoghegan
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Prepared By: Phil Triolo and Associates, LC

2.DEVICE

Trade/Device Name: Creo Electrosurgical System with HS1 Hemostasis Accessory

Common Name: Electrosurgical System

Classification Name: Endoscopic electrosurgical unit and accessories /
Electrosurgical cutting and coagulation device and accessories

Regulation number: 21 CFR 876.4300

Product Code: KNS

3.PREDICATE DEVICES

Boston Scientific Injection Gold Probe, bipolar electrohemostasis catheter (K133933)

ERBE VIO 300 D electrosurgical generator (K083452)

Creo Electrosurgical System including Speedboat RS2 surgical accessory (RS2) (K171983)

4.ASSOCIATED FDA DOCUMENT NUMBER

Q182299

5.SYSTEM DESCRIPTION

The Creo Medical Electrosurgical System with HS1 hemostasis accessory comprises of the following:

- HS1 hemostasis surgical accessory
- Electrosurgical Generator
- Footswitch
- Interface Cable

The Electrosurgical Generator is designed to deliver bipolar radiofrequency (RF) energy and microwave (MW) 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 MW 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.

HS1 is an electrosurgical hemostasis accessory for use with the Creo Medical Electrosurgical Generator only. HS1 is for endoscopic use and provides coagulation and injection of fluids incorporated in a single device. HS1 is for single-use only and provided sterile.

6.INDICATIONS FOR USE

The Creo Electrosurgical Generator is intended to provide radiofrequency (RF) electrosurgical energy for cutting and microwave energy (MW) for coagulation (hemostasis, cauterization) of soft tissue, and is for use only with compatible Creo Medical instruments and accessories.

The HS1 Hemostasis Accessory is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following:

• Peptic Ulcers

• Dieulafoy Lesions

• Mallory-Weiss Tears

• Bleeding Polyp Stalks

• Arteriovenous Malformations (AVMs)

• Angiomata

The HS1 also has irrigation capability. Any other use is not recommended.

7.TCHNOLOGICAL CHARACTERISTICS

The Electrosurgical Generator comprises two distinct energy sources for the independent generation of bipolar RF current at 400 kHz and 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 HS1 surgical accessory is 1.75m long and used through the working channel of a compatible endoscope. The distal tip of the device comprised of:

- Stainless-steel bipolar electrodes that are separated by a PEEK dielectric for delivering coagulation energies.
- A parylene coating for provided a lubricious 'non-stick' coating
- An extendable and retractable needle for delivery and injection of fluids that is user-operated by a slider control located on the proximal handle of the instrument

The proximal handle of the HS1 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 MW frequencies.

8.DIFFERENCES BETWEEN SUBJECT AND PREDICATE DEVICES

Difference	Performance Testing
Coagulation: Energy The predicate device (Gold Probe) uses bipolar RF energy at 350 kHz while the subject device uses MW energy at 5.8 GHz	Bench testing: Comparison with the predicate device for the penetration and spread of thermal effects in gastrointestinal tissue. The bench testing showed substantial equivalence with the predicate device. The difference in coagulation energy raises no new questions regarding safety and efficacy.
Coagulation: Design distal tip The predicate device (Gold Probe) has a dome shaped gold-metallized ceramic distal tip while the subject device has a blade shaped gold-metallized ceramic tip with a metal hull	Bench testing: Comparison with the predicate device for the penetration and spread of thermal effects in gastrointestinal tissue. The bench testing showed substantial equivalence with the predicate device. The difference in the design of the distal tip raises no new questions regarding safety and efficacy.
Shaft and distal tip materials The materials used in the distal tip and shaft of the subject device	Bench testing: Comparison with the predicate devices for the penetration and spread of thermal effects in gastrointestinal tissue. The bench testing showed substantial equivalence with the predicate device.

Difference	Performance Testing
are similar but not identical to the predicate devices	Biocompatibility: Meets all relevant requirements of FDA guidance and ISO 10993. The difference in the shaft and distal tip materials raise no new questions regarding safety and efficacy.
Needle and Injection configuration and materials The materials used in the needle and the internal lumen of the predicate device are similar but not identical to the predicate devices (Gold probe)	Bench Testing: Performance testing of injection flowrate. Performance testing of the insertion and retraction durability the needle can extend and retract throughout lifetime use. The needle continues to perform to specification in a worst-case endoscope position. Performance testing of the needle point sharpness throughout the lifetime use of the device. Performance testing needle to hypotube and ferrule tensile strength. All bench testing showed an acceptable level of performance. Biocompatibility: Meets all relevant requirements of FDA guidance and ISO 10993. The difference in the needle configuration and materials raise no new questions regarding safety and efficacy.

9.PERFORMANCE DATA

The system meets all design specifications, design-risk analysis, and medical device standards for electrical safety and FDA recognized versions of EMC (IEC 60601), electrical safety (IEC 60601), biocompatibility (ISO 10993) and sterility (ISO 11135). The mechanical, coagulation and injection performance in ex-vivo and in-vivo meets the design specification and shows substantial equivalence to the predicate devices.

10.CONCLUSION

The Creo Medical Electrosurgical System with HS1 surgical accessories is substantially equivalent to the Boston Scientific Injection Gold Probe, bipolar electrohemostasis catheter (K133933) and the ERBE VIO 300 D electrosurgical generator (K083452).