



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 17, 2017

Creo Medical Ltd.
% Keith Penny
Director Quality Assurance and Regulatory Affairs
Creo Medical Ltd.
Riverside Court, Beaufort Park
Chepstow, NP16 5UH
United Kingdom

Re: K171983
Trade/Device Name: Creo Medical Electrosurgical System including Speedboat RS2
Surgical Accessory
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS
Dated: June 29, 2017
Received: June 30, 2017

Dear Keith Penny:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171983

Device Name

Creo Medical Electrosurgical System including Speedboat RS2 Surgical Accessory

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5 510(k) SUMMARY

1. SUBMITTER

Creo Medical Ltd
Riverside Court
Beaufort Park
Chepstow
NP16 5UH
United Kingdom
Phone: +44 (0) 1291 606005
Fax: +44 (0) 1291 606015

Contact:
Keith Penny
Director Regulatory Affairs

Date Prepared: June 28, 2017

2. DEVICE

Device Name: Creo Medical Electrosurgical System including Speedboat RS2 surgical accessory
Common Name: Electrosurgical System
Classification Name: Unit, Electrosurgical, Endoscopic (With Or Without Accessories)
Regulation Number: 21 CFR 876.4300
Product Code: KNS
Classification: Class II

3. PREDICATE DEVICES

Olympus Hook Knife, single-use electrosurgical knife	K092309
Boston Scientific Injection Gold Probe, bipolar electrohemostasis catheter	K133933
ERBE VIO 300 D electrosurgical generator	K083452

4. SYSTEM DESCRIPTION

The Creo Medical Electrosurgical System comprises:

- Speedboat RS2 surgical instrument (7-RS2-001)
- Electrosurgical Generator (7-EMR-050)
- Footswitch (2-EMR-032)
- Interface Cable (7-RS2-210)

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 RS2 is an electrosurgical instrument for use with the Creo Medical Electrosurgical Generator only. Speedboat RS2 is for endoscopic use and provides cutting, coagulation and injection of fluids incorporated in a single device. Speedboat RS2 is for single-use only and provided sterile.

5. INDICATION 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.

6. TECHNOLOGICAL 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.

The Speedboat RS2 surgical 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 (Blade) for delivery of cutting and coagulation energies
- a stainless-steel rounded contour component (Hull) mounted to the Blade
- 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 Speedboat RS2 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.

7. DIFFERENCE BETWEEN SUBJECT AND PREDICATE DEVICES

Difference	Performance Testing
<p><u>Cut: Energy</u> The predicate device (Hook Knife) uses monopolar RF energy at 350 kHz while the subject device uses bipolar RF energy at 400 kHz</p>	<p>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 cut energy raises no new questions regarding safety and efficacy.</p>

Difference	Performance Testing
<p><u>Cut: Design distal tip</u> The predicate device (Hook Knife) has a L- shaped stainless steel distal tip while the subject device has a blade shaped gold-metallized ceramic tip with a metal hull</p>	<p>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.</p>
<p><u>Coagulation: Energy</u> The predicate device (Gold Probe) uses bipolar RF energy at 350 kHz while the subject device uses microwave energy at 5.8 GHz</p>	<p>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.</p>
<p><u>Coagulation: Design distal tip</u> 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</p>	<p>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.</p>
<p><u>Shaft and distal tip materials</u> The materials used in the distal tip and shaft of the subject device are similar but not identical to the predicate devices</p>	<p>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. Biocompatibility: Meets all relevant requirements of ISO10993. The difference in the shaft and distal tip materials raise no new questions regarding safety and efficacy.</p>

8. PERFORMANCE DATA

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

9. CONCLUSION

The Creo Medical Electrosurgical System is substantially equivalent to the predicate devices.