January 5, 2021

Creo Medical Ltd.
% Phil Triolo
President and Senior Consultant
Phil Triolo and Associates LC
86 Skycrest Ln
Salt Lake City, Utah 84108

Re: K200298
Trade/Device Name: ABI Instrument, Creo Electrosurgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: December 4, 2020
Received: December 7, 2020

Dear Phil Triolo:

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. 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 post-marketing 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
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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)*
K200298

Device Name
Creo Electrosurgical System with AB1 Accessory

Indications for Use *(Describe)*
The Creo Electrosurgical System is intended to provide microwave energy for coagulation (ablation) of soft tissue and is for use only with compatible Creo Medical instruments and accessories.

The System is not intended for use in cardiac procedures.

The AB1 Instrument, when used with the Creo Electrosurgical System, is intended for use in coagulation (ablation) of soft tissue.

The AB1 Instrument 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.

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510(k) Summary

K200298

Date Prepared: December 4, 2020

1. SUBMITTER

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2. DEVICE

Trade/Device Name: Creo Electrosurgical System with AB1 Accessory

Common Name: Electrosurgical System

Classification Name: Electrosurgical cutting and coagulation device and accessories

Regulation number: CFR 878.4400

Product Code: NEY (Class II)

3. PREDICATE DEVICES

K163105 Emprint Ablation System

4. SYSTEM DESCRIPTION

The Creo Medical (Creo) Electrosurgical System with AB1 Accessory includes the following:

- AB1 Instrument
- Electrosurgical Generator
- Footswitch
- Interface Cable with Sterile Sheaths

The Electrosurgical Generator is designed to deliver bipolar radiofrequency (RF) energy and microwave (MW) energy for the purpose of cutting and coagulating (ablating) tissue. Only the microwave output is used to power the AB1 Instrument. The Electrosurgical Generator output is actuated via a two-pedal Footswitch. One pedal activates the bipolar RF energy output for cutting; the other pedal activates the MW energy output for coagulation. The Electrosurgical Generator incorporates proprietary software developed by Creo for generating and controlling the two energies delivered. The Electrosurgical Generator and Footswitch are non-sterile and reusable.

The single-use Interface Cable connects compatible Creo electrosurgical instruments to the Electrosurgical Generator and is supplied with a sterile sheath that is fitted over its distal end during use to minimize the potential for contamination of the sterile field.

The sterile, single-use AB1 soft tissue ablation accessory (Instrument) consists of a flexible, movable handle and a 0.95 m long x 4.3 mm diameter shaft that terminates in a 38 mm long x 1.9 mm diameter distal antenna with conical tip. Two metallic washers separated by dielectric materials couple microwave energy to target tissue when AB1 is in use. AB1 is only compatible for use with the Creo Electrosurgical System, and the Creo Electrosurgical System is only intended for use with compatible Creo instruments and accessories.

5. INDICATIONS FOR USE

The Creo Electrosurgical System is intended to provide microwave energy for coagulation (ablation) of soft tissue and is for use only with compatible Creo Medical instruments and accessories.

The System is not intended for use in cardiac procedures.

The AB1 Instrument, when used with the Creo Electrosurgical System, is intended for use in coagulation (ablation) of soft tissue.

The AB1 Instrument is not intended for use in cardiac procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Electrosurgical Generator (when used to power the AB1 instrument) is designed to provide microwave energy at 5.8 GHz. These generator output voltage, power, current, duty cycle, and duration are under the control of software and hardware circuits to assure the energy delivered to the AB1 instrument via the Interface Cable is within specifications. When AB1 is connected to the Electrosurgical Generator and selected for use using either the Footswitch or membrane switches on the Generator, only microwave energy is delivered.

The AB1 Instrument is a flexible electrosurgical accessory that employs two metallic washers separated by dielectric materials to couple microwave energy delivered by the generator to target tissue as directed by the user. AB1 is only compatible for use with the Creo Medical Electrosurgical System, and the System is only intended for use with compatible Creo instruments and accessories.

The subject and predicate devices are based on the following same technological elements, as both systems use microwave energy to effect ablation of soft tissue. Both devices utilize the fundamental mechanism for electromagnetic energy coupling to tissue employed by all microwave-powered ablation devices. The interaction between the microwave electromagnetic fields and soft tissue primarily results in rapid oscillation of dipolar water molecules, frictional resistance to such movement, and resultant active localized tissue heating. Thermal conduction, due to the temperature gradient created by the active tissue heating region, results in adjacent tissue heating (thermal spread). The mechanism of microwave energy absorption is known as dielectric heating. For a specified tissue type and microwave frequency, the rate of microwave energy absorption is predictable, which allows for control of the energy absorption and subsequent thermal effects.

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

Difference	**Evidence supporting substantial equivalence**
The AB1 Instrument is supplied with 25 W microwave power at 5.8 GHz whereas the predicate antenna is supplied with microwave power at 2.45 GHz	Results of simulated use studies conducted in ex vivo muscle, liver, lung and kidney tissue were used to characterize the ablation volumes created by the new and predicate systems, which have been determined to be equivalent.
The predicate antenna is actively cooled by water circulated through the antenna; AB1 is not cooled.	Evaluations in ex vivo bovine tissue demonstrate that the temperature of applied parts does not exceed permissible limits and that no non-target tissue is thermally injured as a result of AB1 treatments at its maximum power setting.
Different patient-contacting materials	Results of biocompatibility and performance evaluations demonstrate an acceptable biological risk and that acceptance criteria are met.
AB1 Interface Cable is single use, the predicate cable is reusable	Both cables conduct microwave energy for ablation and neither poses a significant risk for infection.
AB1 System is controlled by software and hardware; the predicate system is only controlled by hardware	EMC, electrical safety, and verification test results demonstrate acceptable safety and performance of the new system.

7. PERFORMANCE DATA

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

Sterilization/Shelf-life

Per ISO 11135 and AAMI TIR28 standard evaluation, the AB1 Sterility Assurance Level is 10-6.

The shelf-life for the AB1 Instrument is 6 months. The shelf life for the Interface Sheath is 3 years.

Biocompatibility

The biocompatibility evaluation for the AB1 Instrument 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.

According to Table A.1: Biocompatibility Evaluation Endpoints in the FDA Biocompatibility Guidance, the antenna assembly of AB1 and the distal portion of its shaft are categorized, from a biological risk perspective, as externally communicating with limited (< 24h) contact with tissue.

The battery of tests whose results support a finding of a low and acceptable biological and toxicological risk included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogen Testing
- Hemolysis

Electrical Safety, Microwave Safety and Electromagnetic Compatibility

Electrical safety and EMC tests were conducted on the Creo Medical Electrosurgical System with AB1 Accessory. 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.

Mechanical and Ablation Performance Testing

- Diameter/weight testing
- Insertion and retraction force testing
- Shaft bending testing
- VNA testing
- Connector compatibility testing
- Thermal profile testing
- Pull testing
- Durability testing
- Heat shrink pull testing
- Standing wave ratio / reflected power threshold testing
- Simulated use testing in ex-vivo tissue (ablation zone repeatability and predicate comparison studies)

Results of mechanical and ablation performance tests, including bench tests and simulated use studies conducted in *ex-vivo* tissue, demonstrate that the AB1 Electrosurgical System meets design specifications and performs as intended, and support Creo’s assertion of substantial equivalence to the predicate device.

8. CONCLUSION

The nonclinical bench testing, simulated use testing, hardware and software verification and validation and standards testing demonstrate there are no new or different questions of safety or effectiveness raised by any differences between the subject device and predicate device. The Creo Medical Electrosurgical System with AB1 Accessory as determined by the indications for use, technological characteristics and the performance testing demonstrate it is as safe and effective as the legally marketed device identified and is substantially equivalent to the identified predicate device.