June 26, 2023

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

Re: K223138
Trade/Device Name: AB1 Electrosurgical 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: September 30, 2022
Received: May 26, 2023

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 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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.06.26 13:08:24 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K223138

Device Name
Creo Electrosurgical System with AB1 Electrosurgical Instrument

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

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

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.

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: June 23, 2023

1.SUBMITTER

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2.DEVICE

Trade/Device Name: Creo Electrosurgical System with AB1 Instrument

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 DEVICE

K200298 – Creo Electrosurgical System with AB1 Accessory

4.DEVICE DESCRIPTION

The Creo Medical (Creo) AB1 soft tissue microwave ablation instrument (electrosurgical instrument, accessory or instrument, also referred to as AB1) is designed for use with the Creo electrosurgical system, previously cleared under K200298. No changes have been made to the Creo generator, footswitch, or interface cable with sterile sheaths that comprise the electrosurgical system, nor are any changes proposed to the AB1 instrument in this 510k.

AB1 is provided as a sterile, single-use instrument that is 0.95 m long with a 4.3 mm diameter shaft that terminates in a distal antenna that is 38 mm long and less than 2.00 mm in diameter (nominally, 1.9 mm) with a conical tip. The AB1 instrument is provided with a flexible, removable (distal) handle. The outer sheath of the flexible shaft may be removed.

This 510k provides instructions to the end user on how to remove the outer extrusion and distal handle to create a configuration that has an outer diameter less than 2.00 mm. The instrument may be used to access target tissue directly, e.g. in open surgical procedures, or, with the handle and outer sheath removed, through a compatible trocar in minimally invasive procedures. The antenna couples microwave energy to target tissue when AB1 is powered by the Creo Electrosurgical System. 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 AB1 Instrument, when used with the Creo Medical Electrosurgical System, is intended for use in coagulation (ablation) of soft tissue.

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

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.

6.COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF THE AB1 WITH MODIFIED IFU WITH THE CLEARED INSTRUMENT

The only change addressed in this 510k is a change to the IFU that instructs the user how to remove the outer sheath and distal handle of the cleared AB1 instrument to create a configuration that has a diameter less than 2.00 mm which can be used with a compatible trocar in minimally invasive procedures. No other changes have been made to the design, materials, or processing of the cleared AB1 instrument.

Attribute	Subject Device	Predicate Device (K200298)
Instrument dimensions	Shaft (with outer sheath): 4.3 mm diameter x 0.95 m length Shaft (without outer sheath): 1.9 mm diameter x 0.95 m length Antenna: 1.9 mm diameter x 38mm length	Shaft (with outer sheath): 4.3 mm diameter x 0.95 m length Antenna: 1.9 mm diameter x 38mm length
Patient contacting materials	Shaft: FEP (Fluorinated Ethylene Propylene) Handle: Silicone Elastomer Sleeve tube: Pebax	Shaft: FEP (Fluorinated Ethylene Propylene) Handle: Silicone Elastomer Sleeve tube: Pebax
Microwave energy supplied	25 W microwave power at 5.8 GHz	25 W microwave power at 5.8 GHz
Device life and sterility	Single-use, delivered in a sterile condition. Sterilized using Ethylene Oxide gas.	Single-use, delivered in a sterile condition. Sterilized using Ethylene Oxide gas.
Pyrogenicity	Non-pyrogenic	Non-pyrogenic

7. PERFORMANCE DATA

In order to address the change in labeling to the device, a risk assessment was conducted that identified that the following tests needed to be conducted to control any new, or increased risks and demonstrate substantially equivalent safety and effectiveness of the configuration created by the user following the revised labeling, to that of the predicate configuration.

- Pull (tensile) test
- Removal of outer extrusion test (effects on underlying cable, cosmetics, electrical performance)
- Insertion and retraction into and from an introducer test
- Shaft bending test
- VNA (vector network analyzer) return loss test
- Thermal profile with introducer test
- Comparison of dimensions of ablations created by new and predicate device in *ex-vivo* tissue
- Preclinical evaluation of safety and performance in a pig model
- Simulated use testing of deployment through introducers
- Electrical safety testing
- Usability engineering validation

The results of the tests conducted and leveraged demonstrate that the AB1 instrument in the proposed configuration with outer sheath and distal handle removed meets all design specifications and applicable medical device standard requirements, and that it is substantially equivalent to the predicate AB1 instrument with the handle and outer sheath in place.

8.CONCLUSION

Results of the bench and preclinical tests conducted demonstrate that the potential risks associated with the configuration of the AB1 instrument created by following the change to the IFU have been reduced to low and acceptable levels. The results further demonstrate that there are no new or different questions of safety or effectiveness raised by the modification to the IFU, and the AB1 instrument in the configuration created following the revised labeling is as safe and effective as the predicate device. Consequently, The Creo Medical AB1 electrosurgical instrument (Accessory) in the configuration created by following the modified IFU is substantially equivalent to the predicate instrument.