February 14, 2023

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

Re: K221672
Trade/Device Name: Creo Electrosurgical System with NP1 Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: June 7, 2022
Received: June 9, 2022

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,

Colin K. Chen -S

Colin Keijing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control 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)*
K221672

Device Name
Creo Electrosurgical System with NP1 Instrument

Indications for Use *(Describe)*

The NP1 MicroBlate Fine Instrument, when used with the Creo Medical Electrosurgical System, is intended for use in coagulation (ablation) of soft tissue.

The NP1 MicroBlate Fine Instrument is not intended for use in cardiac procedures.

The Electrosurgical Generator provides microwave (MW) energy to the compatible Creo Medical AB1 MicroBlate Flex and NP1 MicroBlate Fine instruments, intended for coagulation (ablation) of soft tissue.

The Electrosurgical Generator provides microwave (MW) energy to the compatible Creo Medical HS1 SlypSeal Instrument, intended for coagulation (hemostasis and cauterization) of soft tissue.

The Electrosurgical Generator provides microwave (MW) and radiofrequency (RF) energy to the compatible Creo Medical RS2 Speedboat Instrument, intended for coagulation (hemostasis and cauterization) and cutting soft tissue.

The Electrosurgical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K221672

Date Prepared: February 12, 2023

1. SUBMITTER

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2. DEVICE

Trade/Device Name: Creo Electrosurgical System with NP1 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

K200003 Creo Electrosurgical System with NP1 Accessory

4. SYSTEM DESCRIPTION

The Creo Medical Electrosurgical System with NP1 Instrument includes the following:

- NP1 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 tissue. Only the microwave output is used to power the NP1 Instrument. The Electrosurgical Generator output is actuated via a two-pedal Footswitch. One pedal activates the bipolar RF energy output for cutting (not active for use of NP1); 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 single-use Interface Cable provides a conductive pathway between compatible Creo electrosurgical instruments and the output of the Electrosurgical Generator and is supplied with a sterile sheath that is fitted over the cable's distal end during use to minimize the potential for contamination of the sterile field.

The sterile, single-use NP1 soft tissue ablation instrument consists of a handle, 1.6 m long x 2.7 mm diameter flexible shaft, active nitinol antenna and pointed ceramic tip. Bipolar electrodes separated by dielectric materials couple microwave energy to target tissue when NP1 is activated. NP1 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.

5. INDICATIONS FOR USE

The NP1 MicroBlate Fine instrument, when used with the Creo Medical Electrosurgical System, is intended for use in coagulation (ablation) of soft tissue.

The NP1 MicroBlate Fine Instrument is not intended for use in cardiac procedures.

The Electrosurgical Generator provides microwave (MW) energy to the compatible Creo Medical AB1 MicroBlate Flex and NP1 MicroBlate Fine instruments, intended for coagulation (ablation) of soft tissue.

The Electrosurgical Generator provides microwave (MW) energy to the compatible Creo Medical HS1 SlypSeal Instrument, intended for coagulation (hemostasis and cauterization) of soft tissue.

The Electrosurgical Generator provides microwave (MW) and radiofrequency (RF) energy to the compatible Creo Medical RS2 Speedboat Instrument, intended for coagulation (hemostasis and cauterization) and cutting soft tissue.

The Electrosurgical System 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 NP1 Instrument) is designed to provide microwave energy at 5.8 GHz. The 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 NP1 instrument via the Interface Cable is within specifications. When NP1 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 NP1 Instrument is a flexible electrosurgical accessory that employs bipolar electrodes separated by dielectric materials to couple microwave energy delivered by the generator to target tissue as directed by the user. NP1 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.

This 510k is being submitted to remove a contraindication for transluminal use of the instrument that was required to be included in the instructions for use of the instrument by the FDA. The technological characteristics and specifications of the predicate and modified devices are identical. Microwave energy at 5.8 GHz is delivered to targeted tissue by the NP1 antenna when it is supplied with power by the Generator. 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 heated volume with surrounding tissue, 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.

7. PERFORMANCE DATA

No bench or clinical data were required to demonstrate substantial equivalence with the predicate device or to justify the elimination of the contraindication for transluminal use from the NP1 instrument IFU.

A preclinical study conducted in a porcine model under GLP requirements demonstrates that the NP1 instrument can be transluminally navigated to targeted soft (liver, kidney, pancreas) tissue, deliver microwave energy, and ablate the accessed tissue. Review of the relevant clinical literature and FDA's TPLC database supports the preclinical study results obtained in the preclinical study and the elimination of the transluminal contraindication from instrument labeling.

8. SOFTWARE

The "new" NP1 ,instrument that is the subject of the 510k incorporates software updates and fixes that did not require submission of a new 510k as they did not affect the substantial equivalence to the predicate device.

9. BIOCOMPATIBILITY

The "new" NP1 instrument that is the subject of this 510k did not incorporate any changes in formulation, processing, sterilization, or geometry, and no chemicals were added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) that required additional biocompatibility studies to establish an acceptable biological and toxicological risk.

10. STERILIZATION

The “new”NP1 instrument was adopted, in accordance with the recommendations of AAMI TIR 28, into an EO product family shown to achieve a Sterility Assurance Level of at least 10^{-6}. Sterilization processing conditions were validated in accordance with ISO 11135. The 6-month shelf-life has not changed.

11. STANDARDS

The following standards were referenced in this 510k to support substantial equivalence:

- ANSI AAMI ES60601- 1:2005/(R)2012\\ and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
- IEC 60601-1-2 Edition 4.0 2014-02
- IEC 60601-2-2 Edition 6.0 2017-03
- IEC 60601-2-6 Edition 2.1 2016-04
- IEC 60601-1-6 Edition 3.1 2013-10
- IEC 60601-2-18 Edition 3.0 2009-08
- ISO 10993-1 Fifth Edition 2018-11
- ISO 10993-4 Third Edition 2017-04
- ISO 10993-5 Third Edition 2009-06-01
- ISO 10993-7 Second Edition 2008-10-15/[Amd 1:2019(en)]
- ISO 10993-10:2010 Third Edition 2010-08-01
- ISO 10993-11 Third Edition 2017-09
- ISO 11135 Second Edition 2014-07-15
- IEC 62366-1 Edition 1.0 2015-02 [Including CORRIGENDUM 1 (2016)]
- ISO 14971 Second Edition 2007-03-01
- ANSI/AAMI/IEC 62304:2006/A1:2016

12. CONCLUSION

The information and data provided in K221672 demonstrate that the “new” NP1 Instrument with the contraindication for transluminal use removed is substantially equivalent to and as safe and effective as the predicate NP1 instrument that included a contraindication for transluminal use in its labeling.