October 25, 2019

United States Endoscopy Group Inc.
Mr. Gregory Land
Sr. Regulatory Affairs Specialist
5976 Heisley Road
Mentor, Ohio 44060

Re: K192518
Trade/Device Name: Reusable Monopolar Active Cord
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 12, 2019
Received: September 13, 2019

Dear Mr. Land:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
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)*
K192518

Device Name
Reusable Monopolar Active Cord

Indications for Use *(Describe)*
The Reusable Monopolar Active Cord is intended to deliver monopolar electrical current from the electrosurgical unit to electrosurgical devices or accessories requiring monopolar electrical current during endoscopic 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
For
Reusable Monopolar Active Cord
K192518

United States Endoscopy Group Inc
A Division of STERIS Corporation
5976 Heisley Road
Mentor, OH 44060

Contact: Mr Gregory Land
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Summary Date: September 12, 2019

1. Device Name

Trade Name:	Reusable Monopolar Active Cord
Device Classification:	Class II
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Number:	21 CFR 878.4400
Product Code:	GEI

2. Predicate Device

K982748 New Deantronics, Inc. Model SB 223 and SB 224 BiPolar Cord Sets

3. Description of Device

The Reusable Monopolar Active Cord is used during endoscopic procedures to provide monopolar energy from an Electrosurgical Generator Unit (ESU) to an Active Endoscopic accessory.

The Reusable Monopolar Active Cord consists of a male ESU end and a female device end connected via an insulated cable. The male ESU end uses a bovie style connector to connect to an ESU. The female device side connects to the active connector of an Active Endoscopic accessory.

4. Indications for Use

The Reusable Monopolar Active Cord is intended to deliver monopolar electrical current from the electrosurgical unit to electrosurgical devices or accessories requiring monopolar electrical current during endoscopic procedures.

5. Description of Technological Similarities and Differences

The Reusable Monopolar Active Cord is very similar to Model SB 223 BiPolar Cord Set in Indications for Use and mode of operation. The differences between the Reusable Monopolar Active Cord and the Predicate are the type of energy provided to the device, connection to the Active Endoscopic accessories, and the use life. The predicate device and the proposed device differ in the application of energy. The predicate device is used for Bipolar applications whereas the proposed device is used for Monopolar applications. Monopolar and Bipolar

applications differ in the path the energy takes. In Bipolar applications the active device transmits the energy to an electrosurgical device and completes the electric circuit. In Monopolar applications the active device transmits the energy to an electrosurgical device and a separate return device completes the electric circuit. The differences between Monopolar and Bipolar applications are inconsequential to an Active Cord device because both devices transmit energy from an electrosurgical generator to an electrosurgical device. The connections to Active Endoscopic accessory are different geometries between the proposed and predicate device. Both connections have a conductive insert with an internal diameter capable of connecting to Active Endoscopic accessories, but the proposed device has a step feature to provide an audible click and tactile feedback when connected to an Active Endoscopic accessory. Another difference between the proposed and predicate devices is the use life of the devices. The predicate device is single use and the proposed device is reusable. Although the predicate is single use, the devices are not patient contacting and cleaning instructions are provided to the user in the Instructions for Use. These proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

6. Description of Safety and Substantial Equivalence

Table 5-1 summarizes the difference between the proposed device and the predicate.

Table 5-1. Predicate Device Comparison Table

Feature	**Proposed Reusable Monopolar Active Cord**	**Predicate K982748 New Deantronics, Inc. Model SB 223 and SB 224 BiPolar Cord Sets**	**Comparison**
Indications for use	The active cord is intended to deliver monopolar electrical current from the electrosurgical unit to accessories requiring monopolar electrical current during endoscopic procedures	Electrosurgical accessory. The BiPolar Cord Set for use with foot switching electrosurgical accessories to conduct high-frequency electrical current intended to remove tissue and control bleeding.	Both devices provide a conduit for electrical energy from an electrosurgical unit (ESU) to an accessory requiring electrical current to function. However, the proposed indications are specific for the proposed device and do not mention indications of the devices it may be connected to.
Length	10 feet	10 feet	Identical

Feature	Proposed Reusable Monopolar Active Cord	Predicate K982748 New Deantronics, Inc. Model SB 223 and SB 224 BiPolar Cord Sets	Comparison
Monopolar/Bipolar	Monopolar	Bipolar	Predicate device is Bipolar whereas the proposed device is monopolar
ESU connection	8mm Bovie Style Pin	8mm Bovie Style Pin	Identical
Active Endoscopic accessory connection	Hollow connector with 0.115inch ID and a 0.110inch ID step feature	Hollow connector with a 0.113inch ID	The proposed device has a feature in the Active Endoscopic accessory end to provide the user with audible/tactile feedback when the cord is connected
Provides Audible/Tactile feedback when connected to Active Endoscopic Accessory	Yes	No	The proposed device has a feature in the Active Endoscopic accessory end to provide the user with audible/tactile feedback when the cord is connected
Reusable	Yes	No	The proposed device is reusable and the predicate device is not.
Sterility	Non-sterile	Sterile and non-sterile configurations	The proposed device is supplied non-sterile and the predicate device is supplied in both sterile and non-sterile configurations.

7. Performance Testing

Table 5-2 summarizes the verification activity that was performed with its respective acceptance criteria to verify the safety or effectiveness of the Reusable Monopolar Active Cord.

Table 5-2. Summary of Verification Activities.

Testing	Acceptance Criteria	Proposed Reusable Monopolar Active Cord
Structural Integrity Testing	All Reusable Monopolar Active Cord structural components must, minimally, meet or exceed the structural integrity limits by the predicate active cord	**PASS**
Dimensional	All Reusable Monopolar Active Cord dimensional components must meet the dimensional specification for each active cord	**PASS**
Functional Testing	The Reusable Monopolar Active Cord must function as intended.	**PASS**
Simulation Testing	The Reusable Monopolar Active Cord must provide monopolar energy to hot devices.	**PASS**
Electrical Testing	All Reusable Monopolar Active Cord electrical requirements must meet current industry standards according to IEC 60601-2-2:2017 and IEC 60601-1:2005	**PASS**

8. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device (K982748), Class II (21 CFR 878.4400), product code GEI.