



Food and Drug Administration
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KARL STORZ Endoscopy America Incorporated
Ms. Winkie Wong
Regulatory Affairs Specialist
2151 East Grand Avenue
El Segundo, California 90245

October 9, 2015

Re: K151044

Trade/Device Name: CLICKLINE Scissors Insert for Single Use

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: September 9, 2015

Received: September 10, 2015

Dear Ms. Wong:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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" (21CFR 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 yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151044

Device Name

CLICKLINE Scissors Insert for Single Use

Indications for Use (Describe)

The CLICKLINE Scissor Insert for Single Use is used in combination with a reusable CLICKLINE handle for cutting tissue. Instruments with HF connection can also be used for the monopolar coagulation of tissue or the coagulation of small hemorrhages.

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 OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:	Karl Storz Endoscopy-America, Inc 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Winkie Wong Regulatory Affairs Specialist 424-218-8379 424-218-8519
Date of Preparation:	September 2, 2015
Device Identification:	Trade Name: CLICKLINE Scissors Insert for Single Use Common Name: Electrosurgical, Cutting & Coagulation Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Product Code:	GEI
Regulation:	CFR 878.4400
510(k) Type:	Traditional
Predicate Device(s):	ACE Monopolar Attachment (K123061)
Device Description:	The CLICKLINE Scissors Inserts for Single Use are available in two models, 34310MA-D and 34310MS-D. The two models have the same diameters of 4.9mm with different working lengths of 41.17 cm and 40.7cm, respectively. The jaws of the scissors are made from AISI grade 420 surgical stainless steel. The shafts of the working lengths are manufactured from AISI grade 303 and 304 stainless steel. The tubing and colorant on outer sheath on the working length are made from Apex MTE Medical Grade Polyolefin Tubing and Mevopur-Black, respectively.

Indications For Use:	<p>The CLICKLINE Scissor Insert for Single Use is used in combination with a reusable CLICKLINE handle (K954122) for cutting tissue. Instruments with HF connection can also be used for the monopolar coagulation of tissue or the coagulation of small hemorrhages.</p>
Technological Characteristics:	<p>The predicate and subject devices are both Scissor inserts that are intended to be attached to a handle for monopolar coagulations. There is one minor difference in the physical characteristics in the shaft diameter, 4.9mm vs. 2.35mm. This difference does not raise new question of safety and effectiveness because:</p> <p>The difference in diameter is due to the predicate device's attachment is inserted to a patient-contacting mechanical pencil that has a greater diameter whereas the subject device is attached to the handle that is not patient-contacting. The overall insertion diameters of both the predicate and subject devices are similar (based on predicate literature, one of the ball electrode has a diameter of 5mm.</p> <p>The bench test data for the CLICKLINE Scissor Insert for Single Use demonstrates that the design characteristics used as to achieve its intended use have been met. The results show that the subject device has met all its specifications. The performance validation test report is provided in section 021_Performance Testing of this submission.</p> <p>The minor difference in specifications of the CLICKLINE Scissor Insert for Single Use when compared to the predicate device, ACE Monopolar Attachment by BioEconeer, Inc, do not raise new issues of safety and effectiveness and the devices are substantially equivalent for monopolar coagulation of tissue</p>
Non-Clinical Performance Data:	<p>CLICKLINE Scissor Insert for Single Use is tested according to the following standard:</p> <ul style="list-style-type: none"> • ISO 10993-1 • ISO 10993-5 • ISO 10993-10 • IEC 60601-1 • IEC 60601-2-2

	<ul style="list-style-type: none"> • IEC 60601-2-18 <p>Additional bench testing for performance verification and validation purposes:</p> <ul style="list-style-type: none"> • Charring Test • Thermal Spread Test • Pulling Test • Dropping Test <p>The bench testing performed verified and validated that the CLICKLINE Scissor Insert for Single Use has met all its design specification and is substantially equivalent to the predicate device, ACE Monopolar Attachment, for monopolar coagulation of tissue.</p>
Clinical Performance Data:	No clinical information is required for this submission
Conclusion:	The Karl Storz's CLICKLINE Scissor Insert for Single Use is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe and effective as the legally marketed devices.