DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 22, 2017

Stryker Instruments
Ms. Susanne Galin
Principal Regulatory Affairs Specialist
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K172367
Trade/Device Name: Stryker Integrated Bipolar Cord and Tubing Sets
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 2, 2017
Received: August 4, 2017

Dear Ms. Galin:

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 Part 801); 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 (DICE) 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" (21 CFR 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 (DICE) 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,

Jennifer R. Stevenson -S3

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172367

Device Name
Stryker Integrated Bipolar Cord and Tubing Sets

Indications for Use *(Describe)*
The Stryker Integrated Bipolar Cord and Tubing Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Stryker Integrated Bipolar Cord and Tubing Sets is provided below.

Device Common Name:	Electrosurgical, Cutting & Coagulation & Accessories
Device Trade Name:	Stryker Integrated Bipolar Cord and Tubing Sets
Applicant:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001
Contact:	Susanne Galin Principal Regulatory Affairs Specialist Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 Desk Phone +1 269 389 4132 Cell Phone +1 812 345 7917 Email: susanne.galin@stryker.com
Date Prepared:	**August 21, 2017**
Classification Regulation:	21 CFR §878.4400– Electrosurgical, Cutting & Coagulation & Accessories, Class II
Panel:	General & Plastic Surgery
Product Code:	GEI - Electrosurgical, Cutting & Coagulation & Accessories
Predicate Device:	K890648, Malis Bipolar Cord/Irrigation Tubing Set

Indication for Use:

The Stryker Integrated Bipolar Cord and Tubing Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

Device Description:

The subject devices are the Integrated Tubing and Bipolar Cord Sets. They are integrated irrigation tubing and electrical cord sets to be used with irrigating bipolar forceps, and interface with both the irrigation unit and the electrosurgical generator.

There are two types of sets available from Stryker: one type that is for use with a rotary irrigator unit and one type that is for use with a gravity irrigation unit. Additionally, each type is available with either “flying leads” or a “unitized lead”.

Listing of Subject Devices

Part Number	Item Name	Description
6790-100-001	Integrated Tubing and Bipolar Cord Set, Disposable	Gravity-type, flying lead.
6790-100-002	Integrated Tubing and Bipolar Cord Set, Disposable, Unitized Lead	Gravity-type, unitized lead.
6790-100-003	Bipolar Irrigator Integrated Tubing Set, Disposable	Rotary-type, flying lead.
6790-100-004	Bipolar Irrigator Integrated Tubing Set, Disposable, Unitized Plug	Rotary-type, unitized lead.

Device Comparison Table:

Technological Characteristic	Integrated Tubing & Bipolar Cord Set (as cleared in K890648)	Currently Marketed Gravity Tubing & Bipolar Cord Set	
		Gravity-type	Rotary-type
Electrical Cord Length	12 ft bipolar electrical cord	10.958 ft ± 0.375 ft	10.958 ft ± 0.375 ft
Lead type	flying leads	flying leads and unitized leads	flying leads and unitized leads
Electrical Cord Connector	Female connector which connects to forceps	Female connector which connects to forceps	Female connector which connects to forceps
Irrigation Tubing Length	Total Length: 15 ft irrigation tubing	Total length: 15.833 ft (nominal)	Total Length: 15.583 ft (nominal)
	8.5 inch section serves as pump chamber	8.5 inch serves as pump chamber	5.5 inch serves as pump chamber
Irrigation Tubing Connector	Spike with drip chamber	Spike with no drip chamber	Spike with no drip chamber
	Male Luer connects to forceps (tubing)	Male Luer connects to forceps (tubing)	Male Luer connects to forceps (tubing)
Materials	Silicone tubing – Pump PVC tubing - bag	Silicone tubing – Pump PVC tubing - Bag	Silicone tubing – Pump PVC tubing - Bag
Silicone tubing wall thickness	Not provided in K890648	OD: 0.167” – 0.173” ID: 0.117” - 0.123”	OD: 0.117 (+0.008/-0.0)” ID: 0.028” – 0.035”

Technological Characteristic	**Integrated Tubing & Bipolar Cord Set (as cleared in K890648)**	**Currently Marketed Gravity Tubing & Bipolar Cord Set**	
		Gravity-type	**Rotary-type**
Packaging	Peel pouch, Mylar to Tyvek	Poly bag inside a peel-pouch (60GA BIAX Nylon/2.0 MIL LDPE, Uncoated Tyvek 1073B)	Poly bag inside a peel-pouch (60GA BIAX Nylon/2.0 MIL LDPE, Uncoated Tyvek 1073B)
Sterilization Method	EtO	EtO	EtO
Sterilization Parameters	120° F Temperature 50° F Relative Humidity 750 Mgs. Per liter of Pure EtO 3 hr Gas Exposure 2 Air washes	130° F Temperature Humidity Dwell: 30 min at 4.0”HgA 790 Mg/L 100% EtO 6 hrs 1 min gas exposure 2 Air/nitrogen/steam washes	130° F Temperature Humidity Dwell: 30 min at 4.0”HgA 790 Mg/L 100% EtO 6 hrs 1 min gas exposure 2 Air/nitrogen/steam washes
SAL	10^{-6} SAL	10^{-6} SAL	10^{-6} SAL
Shelf Life	Not provided in K890648	3 years	3 years

Performance Data:

The following summary of V&V Testing is provided to establish substantial equivalence.

V&V Testing Summary	
Biocompatibility	
Cytotoxicity (MEM Elution)	ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity
Systemic Toxicity	ISO 10993-11: 2006 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity
Material Mediated Pyrogenicity	ISO 10993-11:2006, Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.
Irritation/Intracutaneous Reactivity	ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.
Sensitization (Guinea Pig Maximization)	ISO 10993-10:2010. Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.
Cytotoxicity (MEM Elution) after 2X sterilization	ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity

Mechanical and Performance Testing	
Functional Testing of Cord & Tube Set	Functional Testing of Cord & Tube Set after Packaging Testing Testing conducted on: • Unaged Samples • Samples Accelerated Aged to 1.5 years • Samples Accelerated Aged to 3 years Cord Set Durometer Testing Verification PSI Level Testing for Disposable Cable with Tubing, Rotary
Electrical Safety Testing	
Electrical Safety Test Report	ANSI/AAMI ES60601-1:2005, Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance; Consolidated Reprint (2009); Amendment 2 (2010) ANSI/AAMI IEC 60601-1-2:2007(R)2012, Medical Electrical Equipment – Part 1-2: General Requirements for Safety and Essential Performance – Collateral Standard : Electromagnetic Compatibility – Requirements and Tests (Edition 3) ANSI/AAMI IEC 60601-2-2:2009, Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgery Equipment and High Frequency Surgical Accessories
Sterilization Validation	
Sterilization Validation	ANSI / AAMI / ISO 11135: 2014 Sterilization of health care products– Ethylene Oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices.
Packaging Design Verification Testing	
T=0 Design Verification T=1.5 Year Accelerated Aging 60C T=3 Year Accelerated Aging 60C	ASTM D4169, Standard Test Method for Performance Testing of Shipping Containers and Systems ASTM F1886/F1886M, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection ASTM F2096, Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization ASTM F88-15, Standard Test Method for Seal Strength of Flexible Barrier Materials

Substantial Equivalence Conclusion:

As shown in the table above and evidenced by the Verification and Validation Activities described in the submission, the differences in technological characteristics between the currently marketed Integrated Tubing and Cord Sets and the versions cleared in K890648 do not raise new questions of safety and effectiveness, and can be found substantially equivalent.