DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 22, 2016

Stryker Corporation
Mairead Twomey
Senior Staff Regulatory Affairs Specialist
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K153679
Trade/Device Name: Stryker Neptune E-SEP Smoke Evacuation Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 18, 2015
Received: December 21, 2015

Dear Mairead Twomey:

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 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 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,

Jennifer R. Stevenson -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

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)*

K153679

Device Name
Neptune® E-SEP™ Smoke Evacuation Pencil

Indications for Use *(Describe)*

The Neptune E-SEP is an Integrated Smoke Evacuation Pencil (pencil) designed for general electrosurgical applications including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit (generator) to the operative site for the desired surgical effect.

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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4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 324 5412
www.stryker.com

510(k) Summary

Contact Details	
510(k) Owner	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, Michigan 49001 USA Ph: +353-21-4532988 Fax: +1-269-324-5412
FDA Establishment Registration No.	1811755
Contact Person	Mairead Twomey Senior Staff Regulatory Affairs Specialist Ph: +353-21-4532988 Fax: +1-269-389-5412 Mairead.Twomey@stryker.com
Date Submitted	December 18, 2015
Device Name	
Trade Name	Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification	Class II
Primary Classification Name	*Electrosurgical, cutting & coagulation & accessories* (21 CFR 884.4400, Product code GEI)
Reason for 510(k) Submission	Special 510(k) – Device modifications and line extension with no change to fundamental scientific technology or intended use
Device Modification and Line Extension	The line of electrodes offered for use with the Stryker E-SEP Pencil will be expanded to include the following: • Addition of different length of electrodes as well as additional geometries (Needle, Ball, Wire (Loop T-Bar, Loop U-Bar, Conization) – this is a line extension to enable marketing of a more competitive offering • New materials present in new offering of electrodes: ○ ABS Plastic (Polylac PA-757) has been added as a plastic over-mold for longer electrodes ○ Different grade of stainless steel for the rod and tip of the ball and wire [Loop T-Bar, Loop U-Bar, Conization] electrodes This line extension does not change the intended use, indications for use or the fundamental scientific technology of the system.

4100 E. Milham Avenue
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t: 269 323 7700 f: 269 324 5412
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Legally Marketed Predicate Device(s)			
510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**
Predicate			
K143145	GEI	SafeAir Smoke Pencil*	Lina Medical Aps
*SafeAir Smoke Pencil is currently marketed as Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil after acquisition by Stryker in 2014.			
These predicate devices have not been the subject of a design related recall.			

Indications for Use	The Neptune E-SEP is an Integrated Smoke Evacuation Pencil (pencil) designed for general electrosurgical applications including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit (generator) to the operative site for the desired surgical effect.
Device Description	The Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil is a single use monopolar electrosurgical pencil that includes a handpiece with a smoke evacuation function and a range of electrodes (both uncoated and coated). The electrosurgical pencil is compact in size (190 mm long and 17 mm diameter) with 3 m of plastic smoke evacuation tubing and associated electrical cable housed within the tubing. The device is externally powered via an external power generator (supplied by user) connected to a monopolar receptacle using a conventional 3-pin connector. This device remains unchanged from the cleared predicate pencil. The Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil is available in two activation switch configurations, a rocker style and push-button style, which activates monopolar cut or coagulate functions operated by pressing the respective button. The pencil is connected to smoke evacuation tubing which features a dual connector (8 and 22 mm) to allow the user to connect to a variety of smoke evacuation systems including filtration or central vacuum systems, thus minimizing exposure of personnel to surgical smoke plume. Electrodes are available in Blade, Needle, Ball, T-Bar Loop, U-Bar Loop and Conization geometries and are listed in Table 6-1 below.

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Kalamazoo, MI 49001
t: 269 323 7700 f: 269 324 5412
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Table 6-1: Model Numbers and Descriptions of proposed Electrodes

Model Numbers	Model Descriptions
0703-070-000	Neptune ® E-SEP ™ 70mm Blade Electrode Coated *
0703-070-001	Neptune ® E-SEP ™ 70mm Blade Electrode *
0703-125-000	Neptune ® E-SEP ™ 125mm Blade Electrode Coated
0703-125-001	Neptune ® E-SEP ™ 125mm Blade Electrode
0703-165-000	Neptune ® E-SEP ™ 165mm Blade Electrode Coated
0703-165-001	Neptune ® E-SEP ™ 165mm Blade Electrode
0703-007-070	Neptune ® E-SEP ™ 70mm Needle Electrode
0703-120-003	Neptune ® E-SEP ™ 3mm Ball Electrode
0703-120-005	Neptune ® E-SEP ™ 5mm Ball Electrode
0703-213-015	Neptune ® E-SEP ™ Conization Electrode W13 D15 L120
0703-213-020	Neptune ® E-SEP ™ Conization Electrode W13 D20 L120
0703-216-008	Neptune ® E-SEP ™ Conization Electrode W16 D8 L120
0703-216-018	Neptune ® E-SEP ™ Conization Electrode W16 D18 L 120
0703-220-020	Neptune ® E-SEP ™ Conization Electrode W20 D20 L120
0703-310-010	Neptune ® E-SEP ™ Loop T-bar Electrode W10 D10 L120
0703-315-012	Neptune ® E-SEP ™ Loop T-bar Electrode W15 D12 L120
0703-320-015	Neptune ® E-SEP ™ Loop T-bar Electrode W20 D15 L120
0703-320-020	Neptune ® E-SEP ™ Loop T-bar Electrode W20 D20 L120
0703-620-015	Neptune ® E-SEP ™ Loop T-bar Electrode W20 D15 L60
0703-620-020	Neptune ® E-SEP ™ Loop T-bar Electrode W20 D20 L60
0703-720-020	Neptune ® E-SEP ™ Loop U-Bar Electrode W20 D20 L120
*The 70 mm coated and uncoated blade electrodes were previously cleared under K143145, the only change is that these electrodes are offered in an individual packaging configuration.	

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t: 269 323 7700 f: 269 324 5412
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Performance Data (Non-Clinical Tests)	The results of the performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the electrodes for use with the Neptune E-SEP pencil is sufficient for their intended use and support a determination of substantial equivalence to the predicate device.
Summary of Performance Testing	Performance testing was conducted on the proposed devices as determined by the risk analysis for the products. The following areas were evaluated: • Electrical Safety Testing • Functional / Performance Testing • Thermal spread testing • Biocompatibility testing • Sterilization and packaging testing Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the subject devices are sufficient for their intended use and support a determination of substantial equivalence.
Clinical Tests	No clinical testing was deemed necessary for this 510(k).

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Kalamazoo, MI 49001
t: 269 323 7700 f: 269 324 5412
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Table 6-2: *Summary of Predicate Comparison*

Description		SafeAir Smoke Pencil [Predicate] K143145 (Currently marketed as the Neptune® E-SEP™ Smoke Evacuation Pencil)	STRYKER® E-SEP Pencil [Proposed]	Explanation of Difference
Regulatory Information	**510(k)**	K143145	Not yet assigned	**N/A**
	Product Code	GEI	GEI	**Same**
	Indication for Use	SafeAir Smoke Pencil is designed for general electrosurgical applications including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.	The Neptune E-SEP is an Integrated Smoke Evacuation Pencil (pencil) designed for general electrosurgical applications including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit (generator) to the operative site for the desired surgical effect.	**Same.** Stryker Corporation acquired the SafeAir Smoke Pencil in 2014.
	Classification of Device	Class II	Class II	**Same**
	Regulation Number	21 CFR 884.4400	21 CFR 884.4400	**Same**
	Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	**Same**
	Condition of Use	Single Use	Single Use	**Same**
	Type of Use	Prescription Use Only	Prescription Use Only	**Same**
	Patient Population	General	General	**Same**
	Contra - indications	Do not use monopolar electrosurgery on small appendages, as in circumcision or finger surgery.	Do not use monopolar electrosurgery on small appendages, as in circumcision or finger surgery.	**Same**

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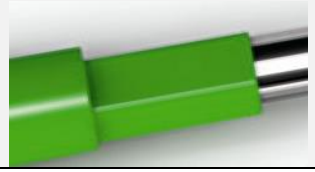
Description		SafeAir Smoke Pencil [Predicate] K143145 (Currently marketed as the Neptune® E-SEP™ Smoke Evacuation Pencil)	STRYKER® E-SEP Pencil [Proposed]	Explanation of Difference
Overall Design Concept	**Overall Design**	Device designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece.	Device designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece.	**Same**
	Power Supply	Monopolar Generator supplied by user	Monopolar Generator supplied by user	**Same**
	Voltage Rating	Maximum 6.0 kV peak	Maximum 5.5 kV peak	**Similar**
	Electrical Connector	US-3-Pin	US-3-Pin	**Same**
	Electrical Safety Testing	IEC 60601-1 IEC 60601-2-2	IEC 60601-1 IEC IEC 60601-2-2	**Same**
	Sterility	Sterile Single Use Only, EtO sterilized SAL = 10^{-6}	Sterile Single Use Only, EtO sterilized SAL = 10^{-6}	**Same**
	Packaging	Single pencil unit with preassembled blade and suction sleeve, holster and clip in an individual Tyvek sealed pouch, sold 10 per box.	Single pencil unit with preassembled blade and suction sleeve, holster and clip in an individual Tyvek sealed pouch, sold 10 per box. Electrodes will also be offered individually packaged in a Tyvek sealed pouch, sold 10 per box.	**Similar**

Description		SafeAir Smoke Pencil [Predicate] K143145 (Currently marketed as the Neptune® E-SEP™ Smoke Evacuation Pencil)	STRYKER® E-SEP Pencil [Proposed]	Explanation of Difference
Electrode Technology and Materials	**Electrode Rod Material**	303 Series Stainless Steel.	303 Series Stainless Steel. This material is being used in 7 of the 21 new electrode rods. The rods of the blade and needle electrodes are made from 303 series Stainless Steel.	**Same**
		This grade of stainless steel was not present in the predicate device.	304 Series Stainless Steel This material is being used in the remaining 14 of the 21 new electrode rods. The rods of the ball, conization and loop electrodes are made from 304 series Stainless Steel.	**Similar**
	Electrode Rod Diameter	2.36 mm	2.36 mm	**Same**
	Electrode Connector Feature	Pentagon Connector 	Pentagon Connector 	**Same**
	Electrode Connector Material	Polypropylene (Bormed RF830MO) 70 mm blade coated	Polypropylene (Bormed RF830MO) 70 mm blade coated & 70 mm needle	**Same**
	Electrode Connector Material	H1500 Polypropylene 70mm Blade Electrode (uncoated)	H1500 Polypropylene 70mm Blade Electrode (uncoated)	**Same**
		Connector material (ABS Polylac PA-757) was not present on the predicate device.	ABS Polylac PA-757 (ABS Plastic) – new connector material present on the Blade, Conization, T-Bar & U-Bar Loop, Ball electrodes.  Electrode Connector	**Different**

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Description		SafeAir Smoke Pencil [Predicate] K143145 (Currently marketed as the Neptune® E-SEP™ Smoke Evacuation Pencil)	STRYKER® E-SEP Pencil [Proposed]	Explanation of Difference
	Electrode Over Mold Insulation (only applicable to longer electrode lengths)	Insulation material (ABS Polylac PA-757) was not present on the predicate device	**ABS Polylac PA-757** is present on longer length electrodes including the 125mm, 165 mm Blade Electrodes, Ball Electrodes, Needle Electrode, T-bar and U-bar Loop Electrodes and the Conization Electrodes.  Electrode Over Mold Insulation	**Different**
	Electrode tip material	303 Series Stainless Steel	303 Series Stainless Steel This material is being used in 7 of the 21 new electrode tips. The tips of the blade and needle electrodes are made from 303 series Stainless Steel.	**Same**
		This grade of stainless steel was not present in the predicate device.	302 Series Stainless Steel 304 Series Stainless Steel	**Similar**
	Electrode tip coating	PTFE (Polytetraflouroethylene)	PTFE (Polytetrafluoroethylene)	**Same**
Electrode Technology and Materials	**Electrode tip working length**	70 mm	70 mm - 165 mm	**Different**
	Electrode tip geometry	Blade (coated and uncoated) 	Blade (coated and uncoated) 	**Same**

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Description		SafeAir Smoke Pencil [Predicate] K143145 (Currently marketed as the Neptune® E-SEP™ Smoke Evacuation Pencil)	STRYKER® E-SEP Pencil [Proposed]	Explanation of Difference
	Electrode tip geometry	Needle Compatibility with the Colorado MicroDissection needle was cleared previously	Needle 	**Same**
		Not applicable – these geometries were not previously cleared	U-Bar, T-Bar, Conization and Ball 	**Different**

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Conclusion/Substantial Equivalence Rationale

The Stryker E-SEP Pencil and Accessories are either identical or similar in intended use, indications for use, technological characteristics, safety and effectiveness to the previously cleared Pencil. The products have the same fundamental scientific technology, basic design, functional characteristics and applications. The modifications and line extension of electrodes introduced raise no new issues of safety and effectiveness.

Therefore, the subject device is at least as safe and effective as the predicate and evidence supports a determination of substantial equivalence.