



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 13, 2016

Stryker Corporation
Mairead Twomey
Associate Regulatory Affairs Manager
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K160693

Trade/Device Name: 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: March 10, 2016
Received: March 14, 2016

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 -

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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)

K160693

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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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 Associate Regulatory Affairs Manager Ph: +353-21-4532988 Fax: +1-269-389-5412 Mairead.Twomey@stryker.com
Date Submitted	March 10 th , 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	<i>Electrosurgical, cutting & coagulation & accessories</i> (21 CFR 878.4400, 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	<p>The following is a list of modifications to the Stryker Neptune E-SEP™ Smoke Evacuation Pencil.</p> <ul style="list-style-type: none"> ○ Addition of three electrodes (70 mm, 125 mm and 165 mm Blade Electrodes)– this is a line extension to enable marketing of a more competitive offering ○ The proposed devices have an additional layer of insulation (PTFE) at the tip of the electrodes: <ul style="list-style-type: none"> ○ PTFE (Polytetrafluoroethylene) has been added via heat shrinking to the proposed electrodes to focus the delivery of the high density current to the distal end of the electrode tip <p>This line extension does not change the intended use, indications for use or the fundamental scientific technology of the system.</p>

Legally Marketed Predicate Device(s)			
510(k) Number	Product Code	Trade Name	Manufacturer
K153679	GEI	Stryker® Neptune® E-SEP™ Smoke Evacuation Pencil	Stryker
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.

Blade electrodes are available coated and insulated and are listed in the below table.

Table 6-1: Model Numbers and Descriptions of proposed Electrodes

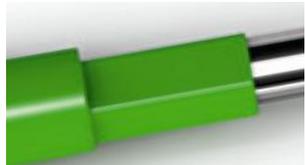
Model Numbers	Model Descriptions
0703-070-002	Neptune [®] E-SEP [™] 70mm Blade Electrode Coated & Insulated
0703-125-002	Neptune [®] E-SEP [™] 125mm Blade Electrode Coated & Insulated
0703-165-002	Neptune [®] E-SEP [™] 165mm Blade Electrode Coated & Insulated

<p>Performance Data (Non-Clinical Tests)</p>	<p>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.</p>
<p>Summary of Performance Testing</p>	<p>Biocompatibility testing was performed on the subject devices in accordance with ANSI/AAMI/ISO 10993-1:2009: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. Results of testing validation the subject device is biocompatible as intended for use.</p> <p>The electrodes for use with the Neptune E-SEP pencil are only available in sterile packaged form. The sterile products will be terminally sterilized using ethylene oxide (EO). The sterilization method was validated and performed in accordance with ANSI/AAMI/ISO 11135:2014, Sterilization of health-care products Ethylene oxide. A sterility assurance of 10⁻⁶ has been validated for these products.</p> <p>Performance testing was conducted on the subject devices as determined by the risk analysis for the products. The following areas were evaluated:</p> <ul style="list-style-type: none"> • 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).

Table 6-2: Summary of Predicate Comparison

Description		STRYKER E-SEP Pencil [Predicate]	STRYKER® Neptune® E-SEP™ Smoke Evacuation Pencil [Proposed]	Explanation of Difference
Regulatory Information	510(k)	K153679	K160693	N/A
	Product Code	GEI	GEI	Same
	Indication for Use	The Neptune E-SEP is an Integrated Smoke Evacuation Pencil (pencil) designed for general electro-surgical applications including cutting and coagulation, and for removing smoke generated by electro-surgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electro-surgical current from the output connector of an electro-surgical unit (generator) to the operative site for the desired surgical effect.	The Neptune E-SEP is an Integrated Smoke Evacuation Pencil (pencil) designed for general electro-surgical applications including cutting and coagulation, and for removing smoke generated by electro-surgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electro-surgical current from the output connector of an electro-surgical unit (generator) to the operative site for the desired surgical effect.	Same
	Classification of Device	Class II	Class II	Same
	Regulation Number	21 CFR 878.4400	21 CFR 878.4400	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 electro-surgery on small appendages, as in circumcision or finger surgery.	Do not use monopolar electro-surgery on small appendages, as in circumcision or finger surgery.	Same

Description		STRYKER E-SEP Pencil [Predicate]	STRYKER® Neptune® E-SEP™ Smoke Evacuation 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 5.5 kV peak	Maximum 5.5 kV peak	Same
	Electrical Connector	US-3-Pin	US-3-Pin	Same
	Electrical Safety Testing	ISO 60601-1 ISO 60601-2-2	ISO 60601-1 ISO 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	Electrodes will be individually packaged in a Tyvek sealed pouch, sold 10 per box.	Electrodes will be individually packaged in a Tyvek sealed pouch, sold 10 per box.	Same
Electrode Technology and Materials	Electrode Rod Material	303 Series Stainless Steel.	303 Series Stainless Steel.	Same
	Electrode Rod Diameter	2.36 mm	2.36 mm	Same
	Electrode Connector Feature	Pentagon Connector 	Pentagon Connector 	Same

Description		STRYKER E-SEP Pencil [Predicate]	STRYKER® Neptune® E-SEP™ Smoke Evacuation Pencil [Proposed]	Explanation of Difference
Electrode Technology and Materials	Electrode Connector Material	ABS Polyac PA-757 (ABS Plastic)  Electrode Connector	ABS Polyac PA-757 (ABS Plastic)  Electrode Connector	Same
	Electrode Over Mould Insulation	ABS Polyac PA-757 (For 125 mm and 165mm blade electrodes)  Electrode Over Mould Insulation	ABS Polyac PA-757 (For 125 mm and 165mm blade electrodes)  Electrode Over Mould Insulation	Same
	Electrode tip material	303 Series Stainless Steel	303 Series Stainless Steel	Same
	Electrode tip coating	PTFE (Polytetrafluoroethylene) (non-stick coating)	PTFE (Polytetrafluoroethylene) (non-stick coating)	Same

Description		STRYKER E-SEP Pencil [Predicate]	STRYKER® Neptune® E-SEP™ Smoke Evacuation Pencil [Proposed]	Explanation of Difference
Electrode Technology and Materials	Electrode tip working length	70 mm - 165 mm	70 mm - 165 mm	Same
	Electrode tip geometry	Blade 	Blade 	Same
	Electrode Tip Insulation	None  Electrode tip	PTFE (Polytetrafluoroethylene) has been added via heat shrinking to the electrodes.  Tip Insulation	Different
Smoke Evacuation Technology and Materials	Adjustable Suction Sleeve Material	Styrene butadiene copolymer Acrylonitrile Butadiene Styrene with barium sulfate	Styrene butadiene copolymer Acrylonitrile Butadiene Styrene with barium sulfate	Same
	Suction Sleeve Lengths	70mm, 125mm, 165 mm	70mm, 125mm, 165 mm	Same
	Evacuation Tubing Dimension	10 mm diameter x 3 m length	10 mm diameter x 3 m length	Same
	Smoke Evacuation System Connector	8mm, 22mm	8mm, 22mm	Same

Description		STRYKER E-SEP Pencil [Predicate]	STRYKER® Neptune® E-SEP™ Smoke Evacuation Pencil [Proposed]	Explanation of Difference
Pencil Technology and Materials	Handpiece Housing Material	Acrylonitrile Butadiene Styrene with Thermoplastic Elastomer	Acrylonitrile Butadiene Styrene with Thermoplastic Elastomer	Same
	Handpiece Dimension	15mm Diameter x 190 mm Length	15mm Diameter x 190 mm Length	Same
	Operation Function Switches	CUT button labeled yellow and proximal to electrode COAG button labeled blue and distal to electrode	CUT button labeled yellow and proximal to electrode COAG button labeled blue and distal to electrode	Same

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.