K 123178

MAR 2 8 2013

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stryker

Instruments

510(k) Summary

1. Contact Details

Applicant Name: Stryker Instruments

Stryker Instruments
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Kalamazoo, MI 49001
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Christina McKee
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Date Prepared: November 8, 2012

2. Device Name

Trade Name: Stryker ® Venom™ Electrodes and Cannulae

Common Name: RF Electrodes and Cannulae

Classification Name: probe, radiofrequency lesion; GXI

3. Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Manufacturer
K032406	GXI	Stryker® Monopolar Electrodes and Cannulae	Stryker Instruments
K060799	GXI	Cosman RF Cannula	Cosman Medical, Inc.

4. Device Description

The Stryker Cannulae will be used in conjunction with the Stryker RF Generator/MultiGen, cables and electrodes to create radiofrequency lesions in nerve tissue. The generator applies

temperature-controlled, radio frequency (RF) energy into targeted nerve tissue via an electrode probe. This energy destroys the nerve tissue's ability to conduct electrical signals. Pain relief is achieved by creating defined lesions on pain-conducting nerve fibers or tissue.

5. Intended Use/Indications for use

The Stryker RF electrodes and cannulae, in combination with the Stryker RF Generator/Multigen, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

6. Substantial Equivalence Comparison

Stryker® Venom™ Electrodes and Cannulae	**Stryker® Monopolar Electrodes and Cannulae (K032406)**	**Cosman RF Electrodes (K082012) and Cannulae (K060799)**	**Comparison**
Electrodes: Nitinol Cannulae: Stainless Steel	Electrodes: Nitinol Cannulae: Stainless Steel	Electrodes: Nitinol Cannula: Stainless Steel	The Stryker Venom™ Electrodes and Cannulae are manufactured from the same materials as the predicate. There are no changes to the material content.
25 gauge (0.5mm OD) Nitinol electrode	27 gauge (0.4mm OD) Nitinol electrode	27 gauge (0.4mm OD) Nitinol electrode	Stryker Venom™ electrode is constructed with a larger diameter nitinol electrode than the predicate Stryker Monopolar electrode and the Cosman electrode. The Venom™ electrode will not be used with a 22 gauge cannula; therefore the gauge of the Venom™ electrode can be slightly larger. The

			difference is size does not change the intended use of the device and does not introduce any new issues of safety and effectiveness.
The Venom™ Cannula consists of 18 or 20 gauge stainless steel tubing cut to length. A bevel tip and a side port are created at the distal end via an electro-chemical grinding process.	The Monopolar Cannula consists of 18, 20 or 22 gauge stainless steel tubing cut to length. A bevel tip is created via an electro-chemical grinding process.	The Cosman RF Cannula consists of a 16 gauge stainless steel tube with an insulated shaft and an exposed tip.	The Stryker Venom™ Cannula has an additional side port at the distal end. The side port allows for diffusion of anesthesia closer to the lesion site and, in conjunction with the electrode, helps to create a lesion size comparable to more invasive, larger gauge cannula and electrodes. The side port does not change the intended use of the device and does not introduce any new issues of safety and effectiveness.

7. Non-clinical Testing

The Stryker® Venom™ Electrodes and Cannulae meet the specification and performance characteristics as identified in Stryker's internal design control procedures and are substantially equivalent to the predicate devices. The testing which was conducted included simulated use, mechanical durability and cleaning. Biocompatibility testing of the Stryker® Venom™ confirmed that the device meets the applicable requirements of the FDA Blue Book Memorandum G95-1 entitled Use of International Standards ISO-10993 Biological Evaluation of Medical Devices Part -1: Evaluation and Testing and are biocompatible.

Bench testing was performed to compare lesion sizes of the 18G Venom™ Cannula using standard electrode deployment and Venom electrode deployment, and the Cosman 16G RF Cannula used with the 27 gauge electrode and Cosman generator. It was determined that the lesion sizes created were smallest for the 18 gauge Venom™ cannula standard deployment

followed by the Venom™ cannula using the Venom deployment. The largest lesion was created by the 16 gauge Cosman cannula and electrode.

8. Clinical Testing

No clinical testing was performed.

9. Conclusions

Based on device comparison information and non-clinical bench testing, the Stryker® Venom™ Electrodes and Cannulae are substantially equivalent to legally marketed predicate devices and do not raise any new concerns of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

Christina McKee
Regulatory Affairs Associate Analyst
4100 East Milham Ave.
Kalamazoo, MI 49001

Re: K123178
Trade/Device Name: Stryker Venom Electrodes and Cannulae
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: II
Product Code: GXI
Dated: February 25, 2013
Received: February 26, 2013

Dear Christina McKee:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if knownK123178

Device Name:

Indications for Use
The Stryker RF electrodes and cannulae, in combination with the Stryker RF Generator/Multigen, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

Prescription Use ____X____ and/or Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
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(Division Sign Off)

Division of Neurological and Physical Medicine Devices (DNPMD)

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