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Kalamazoo, MI 49001
t: 269 323 7700 f: 800 965 6505
www.stryker.com

MAY 3 1 2005

stryker
Instruments

K043442 Page 1 of ②

Summary of Safety and Effectiveness

Device Sponsor: Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700

Registration No.: 1811755

Device Name: Trade Name: Stryker RF Coaxial Bipolar Electrodes and Cannulae
Common Name: Electrosurgical electrode and cannulae
Classification Name: Probe, Radiofrequency Lesion:
21CFR882.4725
Product Code: GXI

Predicate Devices: Stryker RF Electrodes and Cannulae – K032406
Stryker Interventional Pain RF Generator – K032601
Stryker Instruments Neuro N50 – K896450
Bayliss Pain Management Probe – K002389
Smith and Nephew Saphyre Bipolar Ablation Probes – K031371

Description: The Stryker RF Coaxial Bipolar Electrodes and Cannulae will be used in conjunction with the Stryker RF Generator and Connector Cable 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.

The two poles of the bipolar circuit will be referred to as RF1 and RF2. RF1 will define the sending pole while RF2 will define the return pole. Cannulae have both RF1 and RF2 Electrode connections. A secondary conductive surface (RF2) is offset axially to RF1 providing the return path for the RF energy. Thus the RF energy travels from the RF1 pole to the RF2 pole on the same probe. A lesion will be created between RF1 and RF2 on the singular probe.

Intended Use: The Stryker RF coaxial Bipolar Electrodes and Cannulae, in combination with the Stryker RF Generator, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications.

They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

Substantial Equivalence (SE) Rational: The Stryker RF Coaxial Bipolar Electrodes and Cannulae are equivalent in intended use, safety, and effectiveness to existing devices being marketed by Stryker, Smith and Nephew and Baylis.

Safety and Effectiveness: The Stryker RF Coaxial Bipolar Electrodes and Cannulae do not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker RF Coaxial Bipolar Electrodes and Cannulae are substantially equivalent to these existing devices. They will be designed and manufactured in accordance with Stryker Instruments Quality Management System covered by QSR 21CFR 820.

Signed: _____ Dated: _____

Jean W. Sheppard
Regulatory Affairs Analyst

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2005

Stryker Instruments
C/o Mr. Ned Devine
Sr. Staff Engineer
Entela Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K043442
Trade/Device Name: Stryker RF Coaxial Bipolar Electrodes and Cannulae
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXI
Dated: May 13, 2005
Received: May 16, 2005

Dear Mr. Devine:

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.

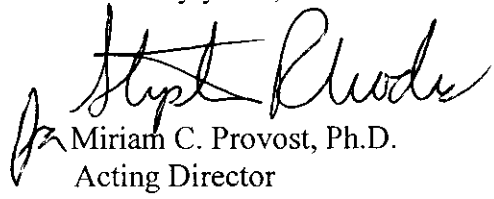
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K043442

Device Name: Stryker RF Coaxial Bipolar Electrodes and Cannulae

Indications For Use:

The Stryker RF Electrodes and Cannulae, in combination with the Stryker RF Generator, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications.

They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

Prescription Use ____X_____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043442