K071482

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510(k) Summary

Device Sponsor: Synergetics, Inc.
3845 Corporate Centre Drive
O'Fallon, MO 63368
(p) 636.794.5013
(f) 636.794.5120

Registration No.: 1932402

DEC 2 0 2007

Trade Name: Stryker RF Multi-lesion Generator

Common Name: Radiofrequency Lesion Generator

Classification Name: Generator, Radiofrequency Lesion (GXD)

Equivalent to: K032601 Stryker Interventional Pain RF Generator
K052878 Neurotherm NT 1000 RF Lesioning System

Device Description:

Stryker RF Multi-lesion Generator

The Stryker RF Multi Lesion Generator will be used in conjunction with Stryker RF Electrodes and Cannula for ablation and coagulation of soft tissue. The generator applies temperature controlled radio frequency RF energy into targeted tissue via an electrode probe, resulting in cellular necrosis. In the case of interventional pain applications, pain relief is achieved by creating defined lesions on pain-conducting nerve fibers or tissue. In addition, the Stryker RF Multi-Lesion Generator allows multiple areas to be targeted and treated concurrently. By treating multiple areas concurrently, overall procedure time can be reduced while maintaining thermal treatments each equivalent to an individual treatment

The Stryker RF Multi-lesion System is a bipolar and monopolar, high frequency electrosurgical system. The System consists of the following components: a RF generator, footswitch hand controller, monopolar and bipolar electrodes, cannulae, neutral electrodes, coaxial bipolar electrodes and cannula, parallel bipolar adapter, connecting cables, and intradiscal cable.

Indications for Use:

Stryker RF Multi-lesion Generator

The Stryker RF Multi-lesion Generator, in combination with the Stryker RF Electrodes and Cannulae are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. Examples include, but are not limited to: Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

The Stryker RF Multi-Lesion Generator in combination with a Smith & Nephew SPINECATH™ & Acutherm™ catheters are intended for coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

Substantial Equivalence (SE) Rational: The Stryker RF Multi-lesion Generator is equivalent in intended use, safety, and effectiveness to existing devices being marketed by Stryker and Neurotherm.

Safety and Effectiveness: Based upon the comparison to the predicate devices, the Stryker RF Multi-lesion Generator is substantially equivalent to a legally marketed device.

Submitted by: Name: Dan Regan
Title: QA/RA Director

Signature

Date submitted: 5-29-07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synergetics, Inc
% Mr. Dan Regan
QA/RA Director
3845 Corporate Centre Drive
O'Fallon, Missouri 63368

DEC 2 0 2007

Re: K071482
Trade/Device Name: Stryker Multi-lesion Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: Class II
Product Code: GXD, GEI
Dated: November 29, 2007
Received: November 30, 2007

Dear Mr. Regan:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071482

Device Name: Stryker Multi-lesion Generator

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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