K063489

MAY 23 2007

510(k) Summary for K063489

Device Sponsor:	Synergetics, Inc. 3845 Corporate Centre Drive O'Fallon, MO 63368 (p)(636) 794-5013 (f) (636) 794-5120
Registration No.:	1932402
Trade Name:	Stryker Intradiscal RF Generator
Common Name:	Radiofrequency Lesion Generator
Classification Name:	Generator, Radiofrequency Lesion (GXD)
Equivalent to:	K033981 Smith & Nephew ElectroThermal 20S Spine Generator
Device Description:	The Stryker Intradiscal RF Generator when used with the separately cleared Stryker RF Intradiscal Adapter and the separately cleared Smith & Nephew SPINECATH™ Intradiscal Catheter (K993967) and ACUTHERM ™ Decompression Catheter is is intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.
Indications for Use:	The Stryker Intradiscal RF Generator is intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The Stryker Intradiscal RF Generator will be used with the previously cleared Stryker RF Intradiscal Adapter and catheters such as Smith & Nephew Spinecath™ & Acutherm™ catheters.
Contraindications	The contraindications for the Stryker Intradiscal RF Generator would be the same as those for the catheter to which it is attached. The contraindications included in the instructions for use for the Smith & Nephew SPINECATH™ Intradiscal Catheter and ACUTHERM ™ Decompression Catheter are:

Use of the SPINECATH™ Intradiscal Catheter is not appropriate for treating patients who present pain that is suspected to originate from structures other than contained herniated discs, or when free fragments or severe bony stenosis are present. In addition, patients presenting severely degenerative or disrupted discs should be excluded.

Use of the Decompression Catheter is not appropriate for treating patients who present pain that is suspected to originate from origins other than herniated discs, or when free fragments or severe spinal stenosis are present. In addition, patients presenting with severely degenerative or disrupted discs should be excluded.

Use of the Smith & Nephew SPINECATH™ Intradiscal Catheter and ACUTHERM ™ Decompression Catheter is appropriate for treating patients with herniations of intervertebral discs who would typically undergo automated or laser percutaneous lumbar discectomy.

Use of the Smith & Nephew SPINECATH™ Intradiscal Catheter and ACUTHERM ™ Decompression Catheter is appropriate for treating patients with herniations of intervertebral discs who would typically undergo automated or laser percutaneous lumbar discectomy.

Precautions:

Patients taking steroids and patients with pacemakers, lupus, gout, uncontrolled diabetes, Ehlers-Danlos syndrome, prior open capsular procedures, autoimmune disease, or etiologies where their immune systems are compromised require special consideration.

Substantial Equivalence (SE) Rational:

The Stryker Intradiscal RF Generator has the same intended use as the Smith & Nephew ElectroThermal 20S Spine Generator (K033981). This device and the predicate device have the same technological characteristics, the same

operating principles and have similar performance characteristics.

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

Submitted by:

Dan Regan
QA/RA Director

Date submitted: **12 March 2007**

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

MAY 23 2007

Re: K063489
Trade/Device Name: Stryker Intradiscal RF Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXD
Dated: May 14, 2007
Received: May 15, 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 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 (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): K063489

Device Name: Stryker Intradiscal RF Generator

Indications for Use: The Stryker Intradiscal RF Generator is intended for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The Stryker Intradiscal RF Generator will be used with the previously cleared Stryker RF Intradiscal Adapter and catheters such as Smith & Nephew Spinecath™ & Acutherm™ catheters.

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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