VALLEY FORGE
SCIENTIFIC

K032601 1/1

APR - 1 2004

Device Name:

Trade Name:	Stryker Interventional Pain RF Generator
Common Name:	Electrosurgical generator
Classification Name:	Generator, Lesion, RF : 21 CFR 882.4400, GXD

Device Sponsor:

Manufacturer:	Valley Forge Scientific 136 Green Tree Rd. P.O. Box 1179 Oaks, PA 2521567

Regulatory Class: Class II

Summary of Safety and Effectiveness:

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

The Stryker Interventional Pain RF Generator is equivalent in intended use, safety, and effectiveness to existing devices being marketed by Oratec, Radionics, Baylis, NeuroTherm, and Arthrocare.

The Stryker Interventional Pain RF Generator does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Interventional Pain RF Generator is substantially equivalent to these existing devices.

By: _____
Jerry Malis
President, CEO

Dated: 3.31.04

136 Green Tree Road
Suite 100
P.O. Box 1179
Oaks, PA 19456
PHONE 610-666-7500
FAX 610-666-7565

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Mr. Jerry Malis
President
Valley Forge Scientific Corp.
136 Green Tree Road, Suite 100
Oaks, Pennsylvania 19456

Re: K032601
Trade/Device Name: Stryker Interventional Pain RF Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXD
Dated: January 30, 2004
Received: February 3, 2004

Dear Mr. Malis:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number: K032601

Device Name: Stryker Interventional Pain RF Generator

Indications For Use:

The Stryker Interventional Pain RF Generator, in combination with the Stryker RF Electrodes and Cannulae, is intended for coagulation of soft tissues in orthopedic, arthroscopic, 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.

Prescription Use X AND/OR Over-The- Counter Use _____

(Per 21 CFR 801 Subpart 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)

Miriam C. Provost

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

510(k) Number K032601

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