K071859

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 20 2007

Device Name

Proprietary Name:	Stryker Crossfire System
Common and Usual Names:	RF and Shaver System
Classification Name:	Arthroscope (21 CFR 888.1100) and Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Product Description: The Stryker Crossfire System consists of a console, footswitch, shaver handpiece and two possible disposable attachments (RF probe and shaver blade).

Indications for Use: The Stryker Crossfire System is intended for use in orthopedic and arthroscopic procedures for the following joints: knee, shoulder, ankle, elbow, wrist, and hip. The Crossfire System provides abrasion, resection, debridement and removal of bone and soft tissue through its shaver blade; and the ablation and coagulation of soft tissue, as well as hemostasis of blood vessels, through its electrosurgical probe. Examples of uses of the product include resection of torn knee cartilage, subacromial decompression, and resection of synovial tissue in other joints.

Contraindications: The electrosurgical probe should not be used in procedures where a nonconductive irrigant is used or with patients having cardiac pacemakers or other electronic implants.

Voluntary Safety and Performance Standards: The Stryker Crossfire System will conform to the following voluntary safety and performance standards including: EN 980, EN 1041, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 62304, IEC 60601-2-2, IEC 60529, G 95-1, ISO 10993-1, EN 550, EN 556-1, ISO 17664, ISO 11607-1, ISO 11607-2 and ISO 14971.

Predicate Devices: The Stryker Crossfire System is substantially equivalent in terms of safety and effectiveness to currently marketed devices including the Stryker CORE (K032303), SERFAS Energy (K041810), and Total Performance Shaver (K973195) Systems.

Substantial Equivalence: When compared to the predicated devices listed above, the Stryker Crossfire System has the same intended use and the technological differences do not raise new questions of safety and effectiveness. Therefore, the Stryker Crossfire System is substantially equivalent to the predicate marketed devices. Refer to Section 7.0 for a detailed comparison.

Contact:

K. Jeffrey Semone
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
Phone: 408-754-2124
Fax: 408-754-2521
Email: jeff.semone@stryker.com

Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2007

Stryker Endoscopy
% Mr. K. Jeffrey Semone
5900 Optical Court
San Jose, California 95138

Re: K071859
Trade/Device Name: Stryker Crossfire System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HRX
Dated: August 28, 2007
Received: August 29, 2007

Dear Mr. Semone:

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,

for Mark N. Melkerson DBP D.A. 9/20/07

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

Enclosure

K071859

INDICATIONS FOR USE

Device Name: Stryker Crossfire System

510(k) Number if known: K071859

The Stryker Crossfire System is intended for use in orthopedic and arthroscopic procedures for the following joints: knee, shoulder, ankle, elbow, wrist, and hip. The Crossfire System provides abrasion, resection, debridement and removal of bone and soft tissue through its shaver blade; and the ablation and coagulation of soft tissue, as well as hemostasis of blood vessels, through its electrosurgical probe. Examples of uses of the product include resection of torn knee cartilage, subacromial decompression, and resection of synovial tissue in other joints.

Contraindications:

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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

510(k) Number K071859