AUG 13 1999

stryker®
ENDOSCOPY

K 991960

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Common and Usual Name:	RF System, RF Generator, RF Console, RF Probe, RF Cable, RF Footswitch
Proprietary Name:	SERFAS System, SERFAS Generator, SERFAS Console, SERFAS Probe, SERFAS Handpiece Cable, SERFAS Footswitch

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker SERFAS is a bipolar electrosurgery system for ablation and coagulation of tissue in presence of a conductive irrigant. The SERFAS system includes a generator, a cable, probes with a variety of tip configurations and a footswitch. The probes are packaged sterile and the generator, cable and footswitch are packaged non-sterile.

The SERFAS system is tested to the following voluntary consensus standards for electrosurgical devices (IEC 60601-2-2 and EN-60601-1). The software in the system conforms to IEC 601-1-4.

The parts of SERFAS contacting the patient are constructed of materials which are tested for biocompatibility per ISO-10993 and General Program Memorandum #G95-1. Sterilization of the SERFAS probes is per EN 550 (EtO) or EN 552 (Irradiation) and sterility is validated for a minimum sterility assurance level of 10^{-6}.

The SERFAS is equivalent in safety and effectiveness to a variety of devices currently marketed including the Arthrocare System 2000 and the Mitek VAPR System. These devices use high frequency current to achieve the intended clinical purpose.

This device does not raise new issues when compared to its predicate devices or uses. Therefore, it is considered substantially equivalent to those devices.

Contact:

N. Mani Prakash, Ph.D.
Senior Design Engineer
Stryker Endoscopy

Date: June 3, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

N. Mani Prakash, Ph.D.
Senior Design Engineer
Stryker® Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K991960
Trade Name: Stryker® Endoscopy Radio Frequency Ablation System (SERFAS)
Regulatory Class: II
Product Code: GEI
Dated: June 3, 1999
Received: June 10, 1999

Dear Dr. Prakash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

June 3, 1999

510(k) Number if known: K991960

INDICATION FOR USE:

The SERFAS RF system is an electrosurgical system designed for general surgical use, including orthopedic and arthroscopic applications of ablation and coagulation of soft tissues, and hemostasis of blood vessels. The system is intended for use in arthroscopic surgery of the joints such as knee, shoulder, elbow, ankle, hip and wrist. The system is intended for use in saline solution, Ringer's lactate or other conductive solution as an irrigant.

(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 Devices
510(k) Number K991960

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)