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DEC 21 2004

stryker®

Endoscopy

K041810

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date December 2, 2004

Device Name

Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Common and Usual Name:	RF System
Proprietary Name:	SERFAS Energy System

Product Description
The SERFAS Energy System is a bipolar high frequency electrosurgical system comprised of an electrosurgical generator, a series of disposable, single use, probe styles, and a footswitch.

Intended Use
The SERFAS Energy System is indicated for resection ablation and coagulation of soft tissue and hemostasis of blood vessels in orthopedic and arthroscopic procedures of joints such as the knee, shoulder, elbow, hip, ankle and wrist.

Predicate Devices
Stryker Endoscopy Radio Frequency Ablation System (SERFAS): K991960
ArthroCare System: K001588, K011634, K020832, K032504
ArthroCare ArthroWands: K011083, K013463, K020557, K030551, K033584
Mitek VAPR System: K974022

Substantial Equivalence
When compared to the predicated devices listed above the SERFAS Energy System has the same intended use and the technological differences do not raise new questions of safety and effectiveness. Therefore, the SERFAS Energy System is substantially equivalent to the predicate marketed devices.

Contact
Christopher Earley
Senior Design Engineer
Stryker Endoscopy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Stryker Endoscopy
c/o Mr. Nishith Desai
TÜV Rheinland of North America, Inc.
12 Commerce Road
Newtown, Connecticut 06470

Re: K041810
Trade/Device Name: SERFAS Energy System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 13, 2004
Received: December 15, 2004

Dear Mr. Desai:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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

Indications for Use

510(k) Number (if known): K041810

Device Name: SERFAS Energy System

Indications for Use:

The SERFAS Energy System is indicated for resection, ablation and coagulation of soft tissue and hemostasis of blood vessels in orthopedic and arthroscopic procedures of joints such as the knee, shoulder, elbow, hip, ankle, and wrist.

Prescription Use __X___ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(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 K041810