K033135 1/1

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AUG - 9 2004

stryker

Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:

- Endoscope and Accessories
- Bone Cutting Instruments and Accessories
- Electrosurgical Cutting and Coagulation Device and Accessories.

Common and Usual Name: Wireless Footswitch

Proprietary Name: Stryker Wireless Universal Footswitch System

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

The Stryker Wireless Universal Footswitch System (SWUFS) is substantially equivalent in safety and efficacy as the currently marketed Stryker Sidne™ System (K022393), Stryker SERFAS System (K991960), and Stryker Total Performance System (K991703).

The Stryker Wireless Universal Footswitch System (SWUFS) is indicated for use with compatible endoscopic and general surgery devices. It will utilize a single footswitch to selectively control multiple devices, which typically each have their own dedicated footswitch. The system includes a wireless footswitch and receiver. The SWUFS will be an accessory to and provide footswitch input control for the Stryker Total Performance System, the SERFAS (Stryker Endoscopy Radio Frequency Ablation System) consoles, and the Valleylab Electrosurgical Generator. The elimination of numerous wires and multiple footswitches within the Operating Room will improve safety and efficiency by centralizing all footswitch controls, uncluttering the OR floor, and reducing set-up and clean-up time.

The Wireless Universal Footswitch System meets the necessary requirements of the following voluntary standards: IEC 60601-1:1988, A1:1991, A2:1995 Medical Electrical Equipment Part 1: General Requirements for Safety; IEC 60601-1-1:2000 Collateral Standard: Safety Requirements for Medical Electrical Systems; IEC 60601-1-2:2001 Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests; IEC 60601-2-2:1998 Particular Requirements for the Safety of High Frequency Surgical Equipment.

The technological differences between the Stryker Wireless Universal Footswitch System and the predicate Stryker Sidne™ System, Stryker SERFAS System, and Stryker Total Performance System do not raise new issues of safety and efficacy of the predicate devices. Therefore, the Stryker Wireless Universal Footswitch System is substantially equivalent to the currently marketed devices.

Michael Hilldoerfer
Design Engineer
Stryker Endoscopy

Date: June 14, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Mr. Michael Hilldoerfer
Design Engineer
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K033135
Trade/Device Name: Stryker Wireless Universal Footswitch System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS, GCJ, HRX, KOG
Dated: July 2, 2004
Received: July 2, 2004

Dear Mr. Hilldoerfer:

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

Indications for Use

510(k) Number (if known): K033135

Device Name: Stryker Wireless Universal Footswitch System

Indications For Use:

The Stryker Wireless Universal Footswitch System (SWUFS) is indicated for use with compatible endoscopic and general surgery devices. It will utilize a single footswitch to selectively control multiple devices, which typically each have their own dedicated footswitch. The system includes a wireless footswitch and receiver. The SWUFS will be an accessory to and provide footswitch input control for the Stryker Total Performance System, the SERFAS (Stryker Endoscopy Radio Frequency Ablation System) consoles, and the Valleylab Electrosurgical Generator.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K033135