



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

JUL 27 2015

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
Dated (Date on orig SE ltr): July 2, 2004
Received (Date on orig SE ltr): July 2, 2004

Dear Mr. Hilldoerfer,

This letter corrects our substantially equivalent letter of August 9, 2004.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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
(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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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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 Hilloerfer
Design Engineer
Stryker Endoscopy

Date: June 14, 2004