K033132

SEP - 2 2004

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Communications

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Common and Usual Name:	Stryker Switchpoint Infinity™ Control System
Proprietary Name:	Switchpoint Infinity™ Control System
Classification Name:	876.1500 – Accessory to Laparoscope, General and Plastic Surgery

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

The Switchpoint Infinity™ Control System is substantially equivalent in safety and efficacy as the currently marketed Sidne™ System and Nurse's Assistant OR Control System. The Sidne™ System was cleared under 510(k)# K022393. The Nurse's Assistant OR Control System was cleared under 510(k)# K010754. The Switchpoint Infinity™ Control System is also substantially equivalent in reference to the teleconferencing feature to the Stryker Switchpoint™ III, a Class I device as determined by 513(g) #C040069, and the KSEA Storz Communication Bus (SCB) Media Control™ already cleared in 510(k) #K020640.

Indications for Use: The Switchpoint Infinity™ Control System is a medical device that is designed to allow direct control of the state, selection, and settings of room equipment, and audio/video equipment and indirect control through the Stryker Endoscopy Sidne™ System of the state, selection, and settings of surgical equipment in the operating room. The Switchpoint Infinity™ Control System is also an integrated voice, video, and data router and teleconferencing interface for the operating room. The intent of the Switchpoint Infinity™ Control System is to allow operating room personnel a center point for controlling all equipment and communication in surgery.

The Stryker Switchpoint Infinity™ Control System is indicated for use with the Stryker Endoscopy Sidne™ System [510(k) # K022393] and Sidne™ compatible endoscopic and general surgery devices. The users of Switchpoint Infinity™ Control System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, urologists, radiologists, and any other surgeon whom requires the use of voice, video, or control in the operating room or a teleconferencing interface.

The Switchpoint Infinity™ Control System conforms to the following voluntary standards: UL 60601-1, 1st Edition (April 25, 2003) Medical Electrical Equipment, Part 1: General Requirements for Safety; EN 60601-1-2 Medical Electrical Equipment Part 1: General Requirements for Safety 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

The technological differences between the Stryker Switchpoint Infinity™ Control System and the predicate devices (Sidne™ System, Nurse's Assistant OR Control System, Switchpoint™ III, and KSEA Storz Communication Bus (SCB) Media Control™) do not raise new issues of safety and efficacy. Therefore, the Stryker Switchpoint Infinity™ Control System is substantially equivalent to the currently marketed Sidne™ System, Nurse's Assistant OR Control System, Switchpoint™ III, and KSEA Storz Communication Bus (SCB) Media Control™.

Laura Murphy
Quality Assurance/Regulatory Affairs Representative
Stryker Communications

Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

Ms. Laura Murphy
Quality Assurance/Regulatory Affairs Representative
Stryker Communications Corporation
12140 Community Road
Poway, California 92064

Re: K033132
Trade/Device Name: Stryker Switchpoint Infinity™ Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 19, 2004
Received: August 19, 2004

Dear Ms. Murphy:

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): K033132

Device Name: Stryker Switchpoint Infinity™ Control System

Indications For Use:

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Prescription Use ___×____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K033132