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OCT 6 - 2005

stryker®
Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name K052141

Proprietary Name:	Stryker Stiletto Electrosurgical Probe
Common and Usual Name:	Electrocautery Probe, Electrosurgical Probe
Classification Name:	Electrosurgical, Cutting & Coagulation Accessories

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

The Stryker Stiletto Electrosurgical Probe is substantially equivalent in terms of safety and effectiveness to currently marketed devices, including the Stryker Strykeflow Electrocautery Probes (K963765).

The Stryker Stiletto Electrosurgical Probe is a new product developed by Stryker. The Stryker Stiletto Electrosurgical Probe is a suction/irrigation probe with electrosurgical capability, composed of stainless steel, thermoplastic polymers (such as polyimide and PTFE) and thermoset polymers (like silicone rubber).

The Stryker Stiletto Electrosurgical Probe is indicated for use in laparoscopic surgical procedures, including laparoscopic general surgery, thoracic surgery, laparoscopic thoracic surgery, gynecological surgery, general surgery and urological surgery. The device allows for suction and irrigation of sterile irrigant solution. In addition, the device is intended to be used for electrosurgical cutting/coagulation during laparoscopic procedures.

The Stryker Stiletto Electrosurgical Probe conforms to the following voluntary safety and performance standards: IEC 60601-2-2 Particular Requirements for the Safety of High Frequency Surgical Equipment, ANSI/AAMI HF-18 Electrosurgical Devices, ISO 10993 Biological Evaluation of Medical Devices, EN 552 Sterilization of Medical Devices – Validation and Routine Control of Irradiation.

There are no significant technological or performance differences between the Stryker Stiletto Electrosurgical Probe and the identified predicate devices (Stryker StrykeFlow Electrocautery Probes, K963765), nor are there any new questions raised regarding safety or effectiveness, therefore, the Stryker Stiletto Electrosurgical Probe is substantially equivalent to the identified predicate devices and surgery systems.

Crystal Ong — Date: 8/5/05
Regulatory Affairs Representative

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2005

Crystal Ong
Regulatory Affairs Representative
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K052141
Trade/Device Name: Stryker Stiletto Electrosurgical Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 5, 2005
Received: August 9, 2005

Dear Ms. Ong:

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,

Barbara Bruehmd

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K052141
Device Name: Stryker Stiletto Electrosurgical Probe

Indications for Use:

The Stryker Stiletto Electrosurgical Probe is indicated for use in laparoscopic surgical procedures, including laparoscopic general surgery, thoracic surgery, laparoscopic thoracic surgery, gynecological surgery, general surgery and urological surgery. The device allows for suction and irrigation of sterile irrigant solution. In addition, the device is intended to be used for electrosurgical cutting/coagulation during laparoscopic procedures.

Contraindications:

The Stryker Stiletto Electrosurgical Probe is not indicated for use in hysteroscopic insufflation procedures. It is not to be used for intrauterine distention as it may result in an embolism.

Prescription Use X 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)

Barbara Bowen MD

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

510(k) Number K052141