JUN 22 2010

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Stryker Bipolar Forceps
Common Name:	Bipolar Forceps
Classification Name and Reference:	Electrosurgical cutting and coagulation device and accessories 21 CFR §878.4400
Proposed Regulatory Class:	Class II
Product Codes:	GEI – Electrosurgical cutting and coagulation device and accessories
For Information contact:	Rob Yamashita Regulatory Affairs Representative Stryker Craniomaxillofacial 750 Trade Centre Way Suite 200 Portage, MI 49002 Phone: (269) 323-4258 / Fax: (877) 648-7114 rob.yamashita@stryker.com
Date Prepared:	June 11, 2010

Description

The Stryker Leibinger range of Bipolar Forceps contains instruments of various lengths, shapes and sizes.

By means of a suitable bipolar cable, the forceps are connected with the bipolar output of an electrosurgery electrosurgical generator. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator activated by a footswitch.

In the course of a surgical intervention, bipolar forceps may also be used to grasp and manipulate soft tissue without the activation of the high frequency current.

The Stryker Bipolar Forceps are reusable and provided non-sterile. All forceps must be cleaned and sterilized prior to every use.

Indications for Use / Intended Use

The Stryker Bipolar Forceps are intended to be used during bipolar electrosurgery to grasp, manipulate and coagulate selected soft tissue. They are connected through a suitable bipolar cable to the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. The Stryker Bipolar Forceps have not been shown to be effective for tubal ligation or tubal cauterization for sterilization procedures and should not be used for these procedures.

Contraindications

The Stryker Bipolar Forceps have not been shown to be effective for tubal ligation or tubal cauterization for sterilization procedures and should not be used for these procedures.

Substantial Equivalence

The Stryker Bipolar Forceps are substantially equivalent to other commercially available bipolar forceps in regards to intended use, design, materials, and operational principles. The following devices are examples of predicate systems:

- Bipolar Forceps (Stingray Surgical Products Inc., K083162)
- Bipolar Coagulation Forceps (Karl Storz, K960009)
- Non-stick Bipolar Forceps (Silverglide Surgical Technologies, K992931)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Stryker Leibinger Gmbh & Co. Kg
% Mr. Rob Yamashita
750 Trade Center Way, Suite 200
Portage, Michigan 49002

JUN 22 2010

Re: K093108
Trade/Device Name: Stryker Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 11, 2010
Received: June 14, 2010

Dear Mr. Yamashita:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093108

Stryker Bipolar Forceps

Indications for Use:

The Stryker Bipolar Forceps are intended to be used during bipolar electrosurgery to grasp, manipulate and coagulate selected soft tissue. They are connected through a suitable bipolar cable to the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. The Stryker Bipolar Forceps have not been shown to be effective for tubal ligation or tubal cauterization for sterilization procedures and should not be used for these procedures.

Contraindications:

The Stryker Bipolar Forceps have not been shown to be effective for tubal ligation or tubal cauterization for sterilization procedures and should not be used for these procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093108