K073450

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510(k) Premarket Notification
Sutter Medizintechnik GmbH
Electrosurgical Cables
510(k) Summary

MAR 17 2008

November 27, 2007

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Subject:	510(k) Summary of Safety and Effectiveness Information for the Sutter Bipolar Electrosurgical Cable
Submitter:	Sutter Medezintechnik GmbH Tullastrasse 87 79108 Freiburg Germany
Proprietary Name:	Sutter Electrosurgical Cables
Common Name and Classification:	Electrosurgical Cutting and Coagulation Device and Accessories (79GEI, §878.4400, Class II)
Device Description:	Sutter Electrosurgical Cables are electrosurgical accessories designed to transfer electrosurgical power to monopolar and bipolar instruments from an electrosurgical generator. The cables are designed to fit standard monopolar/bipolar instruments and generator connectors. Sutter Electrosurgical Cables are supplied non-sterile, and can be reused after cleaning and steam sterilization.
Intended Use:	To electrically connect monopolar/bipolar electrosurgical instruments to an electrosurgical generator.
Test Discussion:	Sutter Electrosurgical Cables presented in this submission are substantially equivalent in design concepts, technologies and materials to their predicate devices. Sutter Electrosurgical Cables were validated through testing that supports the compliance of the devices to the Standards mentioned in Section 17 of this submission.
Test Conclusion:	Sutter Electrosurgical Cables are substantially equivalent to their predicate devices in design concepts, technologies and materials. Testing demonstrates that these devices are as safe, as effective, and perform as well as or better than the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sutter Medizintechnik GMBH
% Boone Interactive
Mr. Thomas A. Boone
Consultant
353 Loma Larga Road
Corrales, New Mexico 87048

MAR 17 2008

Re: K073450
Trade/Device Name: Sutter Monopolar and Bipolar Electrosurgical Cables
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: II
Product Code: GEI
Dated: February 21, 2008
Received: February 29, 2008

Dear Mr. Boone:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

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Indications for Use

510(k) Number (if known): K073450

Device Name: Sutter Monopolar and Bipolar Electrosurgical Cables

Indications for Use: To electrically connect monopolar/bipolar electrosurgical instruments to an electrosurgical generator.

Prescription Use X 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)

Neil R P Ogden for mxm

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

510(k) Number K073450