

Select Medizin-Technik  
Hermann Sutter GmbH

Select-Sutter Micro-Bipolar Forceps

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### 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**Submitter:** Select Medizin-Technik Hermann Sutter GmbH  
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**Contact Person:** Bert Sutter, Vice-President. Sales/Marketing and Product Management

**Date Prepared:** July 21, 1999

**Classification Name:** Electrosurgical Cutting and Coagulation Device and Accessories, Laparoscopic

**Common/Usual Name:** Micro Bipolar Forceps

**Proprietary Name:** Select-Sutter Micro-Bipolar Forceps

**Predicate Device:** MiniSite® Bipolar Forceps, U.S. Surgical Corporation (K972415)

**Device Description:** The Micro-Bipolar Forceps Device is a laparoscopic and endoscopic device used for the grasping and general coagulation/cutting and pinpoint coagulation of tissue using electrosurgical energy under visualization. The device is used with bipolar outputs of electrosurgical generators and has reusable probes for grasping/coagulation and pinpoint coagulation.



OCT 25 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Select Medizin-Technik Hermann Sutter GmbH  
c/o Ms. Anita Thibeault  
Anita Thibeault & Associates  
9070 Bluffview Trace  
Roswell, Georgia 30076

Re: K992760  
Trade Name: Select-Sutter Micro-Bipolar Forceps  
Regulatory Class: II  
Product Code: GEI  
Dated: August 12, 1999  
Received: August 17, 1999

Dear Ms. Thibeault:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

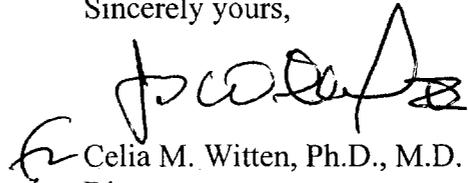
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Ms. Anita Thibeault

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and written over the printed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K992760

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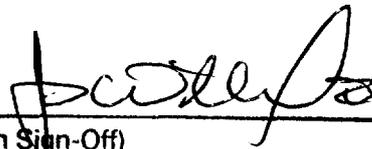
Select-Sutter Micro-Bipolar Forceps

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### INDICATIONS FOR USE

The Select-Sutter Micro-Bipolar Forceps are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general surgery where coagulation of soft tissue is needed. This product is used with bipolar output of standard electrosurgical generators. The types of surgery intended are:

- General surgery
- Laparoscopic procedures
- Endoscopic procedures
- Laryngeal coagulation
- Orthopedic coagulation
- Thorascopic coagulation
- Neurosurgical coagulation
- Gynecological coagulation, (except for use in female sterilization)
- Ear, Nose and Throat coagulation



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992760

Prescription Use X  
(Per 21 CFR 801.109)