

K972008
 Sept. 19, 1997



K972008

SAFETY & EFFECTIVENESS DATA SUMMARY

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
 Common/Usual Name: Electrosurgical Forceps and Electrodes
 Proprietary Name: N/A at this time

Classification: Class II

Electrosurgical cutting and coagulation Device and Accessories

79GE1 Reg. # 878.4400

Electrosurgical Electrodes

79JOS Reg. # 878.4400

Performance Standards: Devices are manufactured according to cGMP's, MIL-STD 105E, AAMI and ASTM requirements, IEC 601 (2-2) and applicable Harmonized Standards.

Material Composition

Material Composition: Surgical grade Stainless Steel (CrNiMo-alloy) certified according to ISO 5832/1 and ASTM 899. Teflon and plastics are identical to the materials used on medicate devices. All of our products are manufactured from medical grade materials.

All materials were selected because of their stability to withstand Steam sterilization.

Testing conducted to assure safety and effectiveness include but is not limited to:

Note: This testing will be completed, reviewed and approved prior to release and distribution of this product.

- Dimensional Verification
- Leak Testing
- Functional Testing
- Visual Inspection
- Bioburden
- Stress/destructive testing
- Accelerated Aging - Shelf Life
- Sterilization

Intended Uses:

The Select-Sutter Electrosurgical Instruments are reusable surgical instruments which have applications in but not limited to; laparoscopic, general, neurologic and thoracic procedures. The Forceps and Electrodes are designed to provide surgeons with an electrosurgical technique for coagulation.

Handwritten signature or initials



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ellen Henke-Knupp
European Surgical, Inc.
73 Eagles Nest Road
Duxbury, Massachusetts 02332

SEP 19 1997

Re: K972008
Trade Name: Electrosurgical Forceps and Electrodes
Regulatory Class: II
Product Code: GEI
Dated: July 18, 1997
Received: July 24, 1997

Dear Ms. Henke-Knupp:

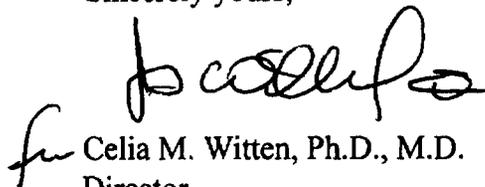
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 requirements, 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,



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



