

SUMMARY OF SAFETY AND EFFECTIVENESS MICRO ELECTRODE INSTRUMENTS

NOV - 5 1997

The Summary of Safety and Effectiveness on Micro Electrode reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Intended Use

The Family of Micro Electrode Instruments are intended for use in laparoscopic minimally invasive surgical procedures to provide monopolar electrocautery capability to dissect and coagulate tissue.

Indications

The incorporation of monopolar electrocautery capability within the instrument provides for cutting and coagulating of intended target tissue sites.

Warning

Do not use any instrument that exhibits insulation degradation. Any damage of the insulation such as dents, scratches, cracking or splitting may allow electric current leakage and cause shock to the patient or doctor.

Caution

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Precaution

The user should take precautions to ensure that all minimally invasive components including laparoscope, endoscope, forceps, trocars and sleeves, electrocautery units, cables, and patient grounding plate are compatible and intended for minimally invasive surgery. It is imperative that all electrosurgical instruments be in contact with or next to the tissue or target prior to activation of the generator to eliminate the possibility of voltage/current seeking an exit through the insulation to the closet "ground". Activate generator only when instrument is in position.

Bench Test

Dielectric Insulation Test @ 3000V - 100% sampling plan.

Substantial Equivalency Information

The Family of Micro Electrode Instruments are similar to the Gynoscope Electrodes

	Gynoscope Electrodes	Micro Electrodes
Materials	Stainless Steel Polyvinylidene fluoride	Stainless Steel Polyvinylidene fluoride

The Micro Electrodes are intended for reuse and following the Cleaning and Sterilization Instructions, sterilization will obtain a Sterility Assurance Level (SAL) of 10^{-6} .

The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Family of Micro Electrodes are comparable to that of the Gynoscope Electrodes.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1997

Ms. Debra A. Pekar
Manager of Quality Assurance and Regulatory Affairs
CooperSurgical
15 Forest Parkway
Shelton, Connecticut 06484

Re: K971838
Micro Electrodes
Dated: October 6, 1997
Received: October 7, 1997
Regulatory class: II
21 CFR §884.4160/Product code: 85 KNF

Dear Ms. Pekar:

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.

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

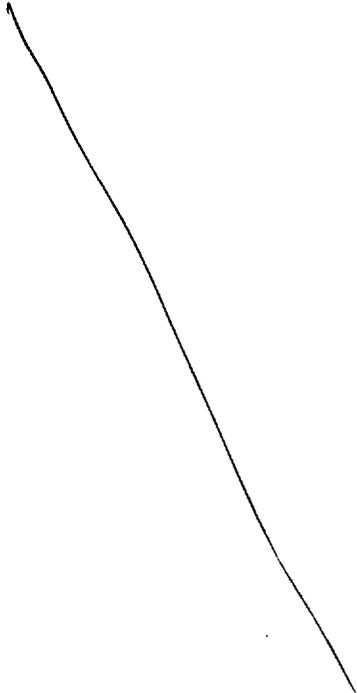
Enclosure

510(k) Number (if known): K971838

Device Name: Family of Micro Electrodes

Indications For Use:

For use in laparoscopic minimally invasive surgical procedures to provide monopolar electrocautery capability to dissect and coagulate tissue.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Sathyan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971838

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use