



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jane Johnson
Regulatory Affairs & Quality Assurance Manger
Electroscope, Incorporated
4828 Sterling Drive
Boulder, Colorado 80301

JAN 16 1998

Re: K972562
Trade Name: Bipolar Electrosurgical Pencil, Straight and Angled
Regulatory Class: II
Product Code: GEI
Dated: October 21, 1997
Received: October 27, 1997

Dear Ms. Johnson:

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.

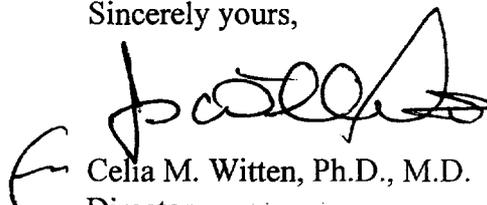
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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 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) 594-4595. 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', is written over the typed 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

ADDITIONAL INFORMATION---K972562

Date: October 13, 1997

Food and Drug Administration
Center for Devices & Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Md. 20856

Ref: "INDICATIONS FOR USE" for the following:

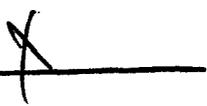
510(k) Premarket Submission, K972562
Bipolar Electrosurgical Pencil-Straight, Catalog No. AE-8000
Bipolar Electrosurgical Pencil-Angled, Catalog No. AE-8001

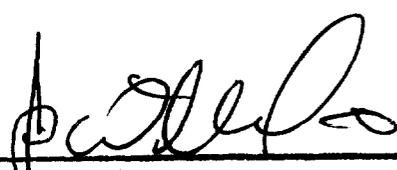
The Electroscope, Inc. Bipolar Electrosurgical Pencil is designed as a "Disposable" product.

The Bipolar Electrosurgical Pencil is a device designed to be used in procedures involving cutting and coagulation of the soft body tissue.

Electroscope, Inc.'s Bipolar Electrosurgical Pencil is a delicate surgical instrument. Any use of the instrument for tasks other than for which it is intended may result in a damaged or broken instrument.

Prescription Use _____
(Per 21 CFR 801.109)





(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____

K972562