GEIGER®
medical technologies

K983852

510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME:	Blue Value Line of Electrosurgical Electrodes
COMMON NAME:	Electrosurgical Electrodes
CLASSIFICATION NAME:	Electrosurgical Cutting and Coagulation Devices (878.4400)

The Blue Value Line of Electrosurgical Electrodes is a line of non-sterile, reusable electrosurgical electrodes designed to be used in conjunction with an electrosurgical generator and handpiece where cutting, blended cutting, coagulation, desiccation, or fulguration procedures are to be performed.

The Blue Value Line of Electrosurgical Electrodes is substantially equivalent to those electrodes previously FDA-cleared for Geiger (K955681 - since sold by Geiger to another manufacturer), to electrodes sold by Geiger under the Electricator product line (preamendment device), to a blade electrode FDA-cleared under K861495, and to a loop electrode FDA-cleared under K944265. The electrodes are also substantially equivalent to electrodes FDA-cleared under K800617. The Blue Value Line of Electrodes is substantially equivalent to the listed FDA-cleared devices in design, operation, intended use, materials, method of preparation, and performance claims.

Furthermore, testing performed on the Blue Value Line of Electrosurgical Electrodes indicates that the devices meet ANSI/AAMI HF-18-1993, Sec. 5.2.5.4 requirements.

In conclusion, the Blue Value Line of Electrosurgical Electrodes is substantially equivalent to the predicate devices in methods of operation, intended use, and results derived from operation.

Submitted By: John Bottjer
President
Geiger Medical Technologies, Inc.
24040 Camino del Avion, A-195
Monarch Beach, CA 92629
(949) 240-7584

Contact Person: John Bottjer
Date: October 28, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 1999

Mr. John Bottjer
President
Geiger Medical Technologies, Inc.
24040 Camino Del Avion, Suite A-195
Monarch Beach, California 92629

Re: K983852
Trade Name: Blue Value Line of Electrosurgical Electrodes
Regulatory Class: II
Product Code: GEI
Dated: October 28, 1998
Received: October 30, 1998

Dear Mr. Bottjer:

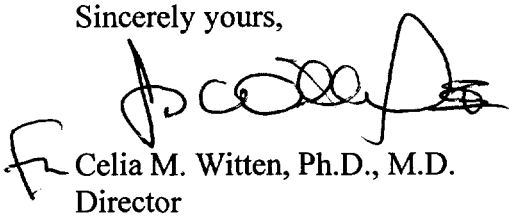
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices 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

510(k) NUMBER (IF KNOWN): K983852

DEVICE NAME: Blue Value Line of Electrosurgical Electrodes

INDICATIONS FOR USE:

Utilized for basic electrosurgical procedures such as cutting, blended cutting, coagulation, fulguration, or desiccation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983852