AUG 19 1999

GEIGER®
medical technologies

K 992149

510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: Geiger Electrosurgical Handpiece Sheath
COMMON NAME: Geiger Electrosurgical Handpiece Sheath
CLASSIFICATION NAME: Device, Electrosurgical, Cutting & Coagulation & Accessories, (878.4400)

The Geiger Electrosurgical Handpiece Sheath is a non-sterile, clear plastic, disposable, electrosurgical handpiece cover, designed to be used over an electrosurgical handpiece to limit contamination.

The Geiger Electrosurgical Handpiece Sheath is substantially equivalent to the ConMed Non-Sterile Handpiece Sheath (510(k) clearance information unknown), and to the ConMed Sterile Handpiece Sheath, FDA-cleared under K963088. The Geiger Electrosurgical Handpiece Sheath is substantially equivalent to the listed devices in design, operation, intended use, materials, method of preparation, and performance claims.

The Geiger Electrosurgical Handpiece Sheaths are also identical in design, materials, method of preparation and performance claims to the Banta Healthcare Products Sanitherm Oral Thermometer Sheaths, FDA-cleared under K983406.

In conclusion, the Geiger Electrosurgical Handpiece Sheaths are 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: June 22, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 1999

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

Re: K992149
Trade Name: Geiger Electrosurgical Handpiece Sheath
Regulatory Class: II
Product Code: GEI
Dated: June 22, 1999
Received: June 24, 1999

Dear Mr. Bottjer:

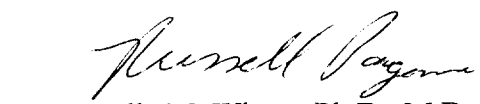
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



for 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): K992149

DEVICE NAME: GEIGER ELECTROSURGICAL HANDPIECE SHEATH

INDICATIONS FOR USE:

The Geiger Electrosurgical Handpiece Sheath is intended to be placed over an electrosurgical handpiece and act as a non-sterile protective barrier. The sheath fits the majority of electrosurgical handpieces utilized in the marketplace.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Russell S. Kayne for JSP

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992149