

DEC 27 1999

# GEIGER®

medical technologies

K994075

1082

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## 510(k) SAFETY AND EFFECTIVENESS SUMMARY

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

The Geiger Disposable Electrosurgical Electrode is a non-sterile, disposable, electrosurgical electrode, designed to be used to deliver electrosurgical current generated by an electrosurgical generator.

The Geiger Disposable Electrosurgical Electrode is substantially equivalent to the E & M Engineering Blade Electrode, cleared under 510(k) K945531. The Geiger Disposable Electrosurgical Electrode is substantially equivalent to the listed device in design, operation, intended use, materials, method of preparation, and performance claims.

In conclusion, the Geiger Disposable Electrosurgical Electrode is substantially equivalent to the predicate device 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: November 30, 1999

**PRODUCT DESCRIPTION:**

The Geiger Disposable Electrosurgical Electrode is a non-sterile, disposable, electrosurgical electrode designed to be used in conjunction with a standard electrosurgical generator and handpiece.

**INTENDED USE:**

The Geiger Disposable Electrosurgical Electrode is intended to be utilized for basic non-sterile electrosurgical procedures. Examples of non-sterile procedures include the removal of moles, warts and skin tags. The electrodes are a standard 3/32" in diameter and will fit the majority of electrosurgical generators and handpieces in the marketplace.

**METHOD OF OPERATION:**

Electrosurgical generators produce a radio frequency current, which is delivered to the patient via an electrosurgical generator, handpiece and electrode. The radio frequency current produces a physiologic effect allowing the physician to cut and coagulate tissue. The type of electrode used is a function of the procedure being performed and the personal preference of the physician.

**ENGINEERING SPECIFICATIONS:**

The Geiger Disposable Electrosurgical Electrodes are manufactured by Modern Medical Equipment Mfg., Ltd. in Hong Kong to Geiger's specifications. An engineering drawing providing specifications is provided in Appendix A-1.

**BIOCOMPATIBILITY:**

During an electrosurgical procedure, the Polystyrene insulation material will not normally come in contact with the patient (momentary patient contact is made only by approximately 1/16" of the tip of the electrosurgical electrode delivering the electrosurgical current). Information regarding the chemical makeup of the stainless steel electrode and Polystyrene insulation is contained in Appendix A-2

Based on the information supplied, Geiger Medical Technologies, Inc. considers the Geiger Disposable Electrosurgical Electrode to be a safe and effective product.



DEC 27 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K994075  
Trade Name: Disposable Electrosurgical Electrode  
Regulatory Class: II  
Product Code: GEI  
Dated: November 30, 1999  
Received: December 2, 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.

Page 2 – Mr. John Bottjer

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 James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K994075

DEVICE NAME: ~~Geiger Disposable Electrosurgical~~ Electrode

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   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use   
(Optional Format 1-2-96)

*Harold J. Payne Jun 57 17*  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K994075