U.S. Food and Drug Administration
510K Document Mail Center HFZ-401
Center for Medical Devices
1390 Piccard Drive
Rockville, Maryland 20850

AUG 27 1997

K972299

To: Document Control Clerk

This summary of 510K safety and effectiveness for the Bergen Model 500 electrosurgery generator is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

An isolated output monopolar electrosurgery generator with independent bipolar electrosurgery generator. The monopolar generator has continuously adjustable 0-150 watts in three cut modes of cut, blend 1, blend 2 and two coagulation modes 0-75 watts. The bipolar generator is continuously adjustable 0-50. Outputs of both generators are independently controlled and RF isolated from each other.

The monopolar electrosurgery generator is similar to the Bergen Model 710 K945861 but without digital displays and calibrated to higher power levels. The bipolar generator is similar to the Bergen Model 610 K964736 but without digital power setting display and current monitor.

Each generator handswitch system is powered by independent low voltage (7 Vdc) isolated power supplies.

Audio and Visual monitors are in accord with IEC 601-1-2 and ANSI HF-18 guidelines.

RF and Low Frequency leakages are well within IEC 601-1-2 and ANSI HF-18 safety guide lines for isolated (body floating) bipolar coagulators.

This device is similar to existing approved devices each as independent generators and in combination.

Sincerely,

Roger Oosten

Roger Oosten
President
Bergen Mfg.
9345 Rookery Road
New Port Richey, Florida 34654

Date 6/12/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Roger Oosten
President
Bergen Manufacturing
9345 Rookery Road
New Port Richey, Florida 34654

AUG 27 1997

Re: K972299
Trade Name: Bergen Model 500 Electrosurgery Generator
Regulatory Class: II
Product Code: GEI
Dated: June 12, 1997
Received: June 19, 1997

Dear Mr. Oosten:

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.

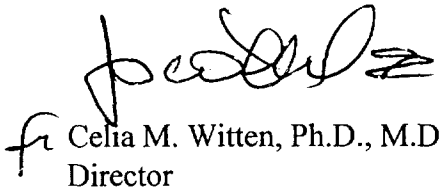
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



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) K972299

Device Name: BERGEN MODEL 500 ELECTROSURGERY GENERATOR

Indications for use: REVISED 7/30/97

The Bergen Model 500 Generator is a general purpose solid state generator to supply the RF signal to electrosurgical handpieces used on soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972299

Prescription Use √ OR Over The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)