

MAY 3 0 2000



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November 4, 1999

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES
Center for Devices and Radiological Health
Document Control Center (HFZ-404)
9200 Corporate Boulevard
Rockville, MD 20850

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K993991.

1. Submitter Identification.

Jhoana Vasquez
Regulatory Affairs
HILL-MED, Inc.
7217 N.W. 46th Street
Miami, Florida 33166

2. Name of the Device:

HM-930 Electrosurgical Unit.
Common Name: Electrosurgical Unit.
Classification Name: Solid State Electro surgical Unit
Class: II
Classification number: 79HAM, Regulation # 878.4400

3. Predicate Device Information:

HM-880 Electrosurgical Unit.
K961473, Hill-Med Corporation, 7217 N.W. 46th Street, Miami, Florida 33166.

4. Device Description:

The HM-930 Eletrosurgical unit has been design to provide the broadest possible range of electrosurgical capabilities. This unit provide monopolar cutting and coagulation capabilities for most demanding procedures. This device can be used for multi-purposes and has the capabilities necessary to perform any particular need.

5. Intended Use:

The HM-930 Electrosurgical Unit is to be used in order to cut and coagulate the skin in surgical procedures.

6. Comparison to Predicated Device:

The HM-930 Electrosurgical unit is used in exactly same manner as HM-880II Electrosurgical unit, both units are intended to be used to cut and coagulate the skin in surgical procedures.

The HM-930 has an RF Output Waveforms of 500 Khz (\approx 10%) while the HM-880II unit has 300 Khz (\pm 10%), both units have cutting coagulation and bipolar outputs, both units have visuable and audible alarm to advise when patient plates cables are disconnected, both units are real digital output display.

7. Conclusion:

Based upon the aforementioned information, the Hill-Med HM-930 Electrosurgical unit is substantially equivalent and is used in exactly the same manner as Hill-Med HM-880II Electrosurgical unit.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jhoana Vasquez
Regulatory Affairs
Hill-Med Corporation
7217 N.W. 46th Street
Miami, Florida 33166

Re: K993991
Trade Name: HM-930 Electrosurgical Unit
Regulatory Class: II
Product Code: GEI
Dated: May 2, 2000
Received: May 4, 2000

Dear Ms. Vasquez:

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.

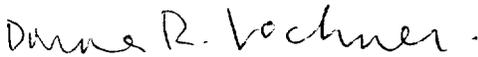
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Unknown~~ K99 3991

Device Name: HM-930 Electrosurgical Unit.

Indications For Use:

The HM-930 Electrosurgical unit is to be used in order to cut and coagulate the skin in surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise R. Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993991

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____