DEC 30 1998

AARON MEDICAL INDUSTRIES, INC. 510(K) NOTIFICATION
Aaron Electrosurgical Handcontrol Pencil

K983761

510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: Aaron Electrosurgical Handcontrol Pencil
COMMON NAME: Electrosurgical Handcontrol Pencil
CLASSIFICATION NAME: Electrosurgical cutting and Coagulation Devices and Accessories (21 CFR 878:4400)

The **Aaron Electrosurgical Handcontrol Pencil** is a sterile, limited reuse electrosurgical handcontrol pencil. It utilizes an insert-molded body that encapsulates a printed circuit board used to sense either CUT or COAG button activation thus activating an electrosurgical generator. It is an accessory to an electrosurgical generator.

The **Aaron Electrosurgical Handcontrol Pencil** is intended to be used in general electrosurgical applications for cutting and coagulating during surgical procedures. It is provided sterile and is intended for limited reuse.

The **Aaron Electrosurgical Handcontrol Pencil** is **IDENTICAL to the Medtrex Encore Electrosurgical Handcontrol Pencil, cleared under K970039 dated February 26, 1997.** It is substantially equivalent to the Valleylab Model E2502B cleared under 510(k) K914400, and the Aaron Medical Industries, Inc Model A801 monopolar handpiece cleared under 510(k) K955681in design, operation, intended use, materials, components and performance claims.

Testing which has been performed on the **Aaron Electrosurgical Handcontrol Pencil** indicates that the devices are substantially equivalent in their performance and method of operation.

Hazard analysis evaluations where performed on the **Aaron Electrosurgical Handcontrol Pencil.** Test results indicated that there are no new hazards presented with the use of the **Aaron Electrosurgical Handcontrol Pencil** as compared with the predicate devices.

In conclusion, the **Aaron Electrosurgical Handcontrol Pencil** is substantially equivalent to the predicate devices, the Medtrex Encore Model 35001-001, the Aaron Medical Industries, Inc Model A801 monopolar handpiece and the Valleylab Model #2502B.

Submitted By: J. Robert Saron
President & CEO
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1998

Mr. J. Robert Saron
President and Chief Executive Officer
Aaron Medical Industries, Inc.
7100 30th Avenue North
St. Petersburg, Florida 33710-2902

Re: K983761
Trade Name: Aaron Electrosurgical Handcontrol Pencil
Regulatory Class: II
Product Code: GEI
Dated: October 23, 1998
Received: October 26, 1998

Dear Mr. Saron:

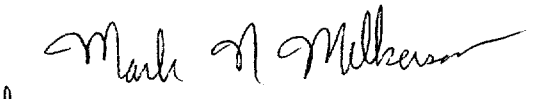
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K983761

Device Name: Aaron Electrosurgical Handcontrol Pencil

Indications For Use:

The Aaron Electrosurgical Handcontrol Pencil is intended to be used in general electrosurgical applications for cutting and coagulating during surgical procedures. It is provided sterile and is intended for limited reuse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Mark N Milhein

(Optional Format 1-2-96)

for CMW (Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____