2/10/99

K984236

AARON MEDICAL INDUSTRIES, INC. 510(K) NOTIFICATION
Aaron ESU Foot Control Adapter #A1205A

510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: Aaron ESU Foot Control Adapter #A1205A
COMMON NAME: Adapter Plug
CLASSIFICATION NAME: Electrosurgical cutting and Coagulation Devices and Accessories (21 CFR 878:4400)

The **Aaron ESU Foot Control Adapter** is a non-sterile, reusable device. It utilizes an insert-molded body that allows a foot-controlled pencil or suction/coagulation tube. The foot control adapter plug allows activation of the Aaron 1200 electrosurgical generator cleared under K980366 dated January 29, 1998. It is an accessory to the Aaron 1200 electrosurgical generator.

The **Aaron ESU Foot Control Adapter** is intended to be used with the Aaron 1200 electrosurgical generator. The adapter will allow the use of a disposable foot-controlled pencil or suction irrigator with a single pin connector with the Aaron 1200 electrosurgical generator. It is non-sterile and is reusable.

The **Aaron ESU Foot Control Adapter** while allowing the use of single pin foot controlled pencils, does not change the design, operation, intended use, materials, components and performance claims of the Aaron 1200 electrosurgical generator cleared under K980366 dated January 29, 1998.

Testing which has been performed on the **Aaron ESU Foot Control Adapter** indicates that the use of the Adapter does not change the operation of either the Aaron 1200 or the foot controlled devices. Consequently, the devices remain substantially equivalent in their performance and method of operation.

Hazard analysis evaluations were performed on the **Aaron ESU Foot Control Adapter.** Test results indicated that there are no new hazards presented with the use of the **Aaron ESU Foot Control Adapter.**

In conclusion, the **Aaron ESU Foot Control Adapter** is an accessory to the Aaron 1200 and will allow the doctor to choose between the reusable pencil included with the Aaron 1200 or a single use disposable foot controlled pencil or suction coagulator.

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

FEB 10 1999

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

Re: K984236
Trade Name: Aaron ESU Foot-Control Adapter #A1205A
Regulatory Class: II
Product Code: GEI
Dated: November 23, 1998
Received: November 25, 1998

Dear Mr. Saron:

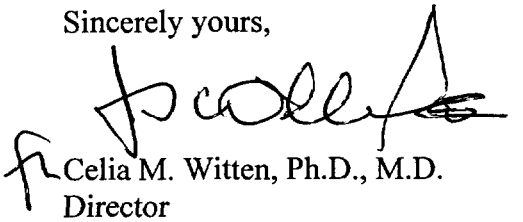
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K984236

Device Name: Aaron ESU Foot-Control Adapter

Indications For Use:

The Aaron ESU Foot-Control Adapter will allow a single pin foot controlled pencil or suction / coagulator to be used with the Aaron 1200 Electrosurgical Generator for cutting or coagulating procedures.

(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 K984236

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

(Optional Format 1-2-96)