

SEP 14 1998

K981570

AARON MEDICAL INDUSTRIES, INC.
Aaron 1200 High Frequency Electrosurgical Generator

510(K) NOTIFICATION
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510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: Aaron 1200 High Frequency Electrosurgical Generator and Accessories
COMMON NAME: Electrosurgical Generator
CLASSIFICATION NAME: Gynecologic electrocautery and accessories (21CFR 884.4120)

The Aaron 1200 High Frequency Electrosurgical Generator is a non-sterile, reusable electrosurgical generator which is designed to generate high frequencies (RF) of high voltage and low amperage current.

The Aaron 1200 High Frequency Electrosurgical Generator is intended for the removal and destruction of human tissue and the coagulation of bleeders. Modes of operation for this device include: cut, blend, coagulation, bipolar, and fulguration. The Handcontrol pencil is an integral component which is used in conjunction with the Aaron 1200.

The Aaron 1200 High Frequency Electrosurgical Generator is substantially equivalent to the Aaron 1200 High Frequency Electrosurgical Generator (K980366), the Aaron 800 High Frequency Desiccator (K955681) and ValleyLab SSE4 Electrosurgical Generator (K823924) in design, operation, intended use, materials, energy source, components, method of preparation and performance claims.

Testing which has been performed on the Aaron 1200 High Frequency Electrosurgical Generator indicates that the devices are substantially equivalent in their performance and method of operation.

Hazard analysis evaluations were performed on the Aaron 1200 High Frequency Electrosurgical Generator. Test results indicated that there are no new hazards presented with the use of the Aaron 1200 High Frequency Electrosurgical Generator as compared with the predicate devices.

In conclusion, the Aaron 1200 High Frequency Electrosurgical Generator is substantially equivalent to the predicate devices, the Aaron 1200 High Frequency Electrosurgical Generator, the Aaron 800 High Frequency Desiccator and the ValleyLab SSE4 Electrosurgical Generator in methods of operation, intended use, and results derived from operation.

Submitted By: J. Robert Saron
President & CEO
Aaron Medical Industries, Inc.
7100 30th Avenue North
St. Petersburg, FL 33710-2902
(813) 384-2323

Contact Person: J. Robert Saron
Date: April 29, 1998





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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. J. Robert Saron
President & CEO
AARON MEDICAL INDUSTRIES, INC.
7100 30th Avenue North
St. Petersburg, FL 33710-2902

Re: K981570
Aaron 1200 HF Electrosurgical Generator
Dated: August 11, 1998
Received: August 12, 1998
Regulatory Class: II
21 CFR 878.4400/Procode: 79 GEI
21 CFR 884.4120/Procode: 85 HGI

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 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): (k)981570

Device Name: Aaron 1200 High Frequency Electrosurgical Generator, Models A1200 & A1200/240

Indications For Use:

The Aaron 1200 is intended to be used for large loop excision of the transformation zone, loop electrosurgical excision procedures and other similar low powered procedures in the area of obstetrics and gynecology. LLETZ is indicated for those patients who have had an abnormal pap smear report with cytologic evidence of CIN, colposcopic examination of the cervix with unsatisfactory findings and who, in the physician's opinion are suitable candidates for the procedure. Indications for the LLETZ procedure include::

- a cytological and colposcopic suspicion of CIN
- a transformation zone which is fully visible and fully confined to the cervix
- a suspicion (cytological or colposcopic) of glandular abnormalities
- a recurrent and troublesome cervical infection with persistent atypicality
- a disparity between the cytological and colposcopic diagnosis
- a suspicion supported by evidence (cytological or colposcopic) of microinvasive disease

(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)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number 981570