2/10/99

K984239

AARON MEDICAL INDUSTRIES, INC. 510(K) NOTIFICATION
Aaron SlickTip Solid Laparoscopic Electrodes

510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: Aaron SlickTip Solid Laparoscopic Electrode
COMMON NAME: Laparoscopic Electrode
CLASSIFICATION NAME: General and Plastic Surgery (21 CFR 878.4400)

The **Aaron SlickTip Solid Laparoscopic Electrode** is a sterile, single use solid laparoscopic electrode. It utilizes an insulated stainless steel laparoscopic electrode with the same coating as cleared under K974735. It is an accessory to an electrosurgical generator.

The **Aaron SlickTip Solid Laparoscopic Electrode,** is intended to be used, in laparoscopic electrosurgical applications for cutting and coagulating during surgical procedures. It is provided sterile and is intended for single use.

The **Aaron SlickTip Solid Laparoscopic Electrode** is **IDENTICAL to the Resistick Solid Laparoscopic Electrodes by Aaron Medical Industries, Inc, cleared under K971621 dated June 20, 1997 with the coating cleared under K974735.** It is substantially equivalent to the MegaDyne K913281, the Valleylab K904560, the Conmed K942892 and the WJ Surgical Hi-Tip Laparoscopic electrodes in design, operation, intended use, materials, components and performance claims.

Testing which has been performed on the **Aaron SlickTip Solid Laparoscopic Electrode** indicates that the devices are substantially equivalent in their performance and method of operation.

Hazard analysis evaluations were performed on the **Aaron SlickTip Solid Laparoscopic Electrode.** Test results indicated that there are no new hazards presented with the use of the **Aaron SlickTip Solid Laparoscopic Electrode** as compared with the predicate devices.

In conclusion, the **Aaron SlickTip Solid Laparoscopic Electrode** is substantially equivalent to the predicate devices, the MegaDyne K913281, the Conmed K942892, the Aaron Medical Industries, Inc Resistick Solid Laparoscopic Electrode K971621,with the Aaron Medical Industries, Inc coating cleared under K974735, the Valleylab K904560 and the WJ Surgical Hi-Tip Laparoscopic electrodes.

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, Inc.
7100 30th Avenue North
St. Petersburg, Florida 33710

Re: K984239
Trade Name: Slicktip Solid Laparoscopic Electrodes
Regulatory Class: II
Product Code: GEI
Dated: November 25, 1998
Received: November 27, 1998

Dear Mr. Saron:

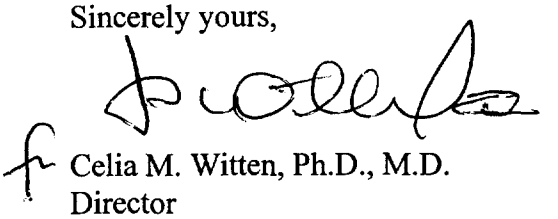
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K984239

Device Name: SlickTip Solid Laparoscopic Electrodes

Indications For Use:

The Subject device of this premarket notification submission is indicated for use to cut and or coagulate during laparoscopic surgical 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 K984239

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

(Optional Format 1-2-96)