FEB 2 2 2006

K060117

ATTACHMENT 5

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Trade Name:	Bovie Remote Hand Switch
Common Name:	Hand Switching Device
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (per 21CFR 878.4400)

The Bovie Remote Hand Switch is a sterile, single-use electrosurgical accessory that is used to activate the CUT and COAGULATION modes of an electrosurgical generator, which operates an attached monopolar accessory. The switch also serves as the connection between a monopolar electrosurgical accessory and the generator. The Bovie Remote Hand Switch provides an alternative to the use of footswitch control to deliver RF energy to an attached monopolar accessory.
The Bovie Remote Hand Switch is substantially equivalent to the Valleylab Inc. E0520 Trigger Switch and Cord (K970140) in operation, intended use, materials, energy source, components, and safety/performance claims.

Testing performed on the Bovie Remote Hand Switch indicates that the device is substantially equivalent in its performance and method of operation to the Valleylab Inc. E0520 Trigger Switch and Cord (K970140). Hazard analysis evaluations were performed on the Bovie Remote Hand Switch. There are no new hazards presented with the use of the Bovie Remote Hand Switch as compared with the predicate device. Both the Remote Hand Switch and the predicate device were designed and tested to meet the ANSI/AAMI HF18 Electrosurgical Device standard.

In conclusion, the Bovie Remote Hand Switch is substantially equivalent to the predicate device (Valleylab Inc. E0520 Trigger Switch and Cord (K970140)) in methods of operation, intended use, and results derived from operation.

Submitted By: Richard Kozloff
Vice-President; Quality Assurance/Regulatory Affairs

Aaron Medical
7100 30th Avenue North
St. Petersburg, FL 33710

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Contact Person: Richard Kozloff

Date: August 29, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2006

Aaron Medical Industries
c/o Mr. Neil E. Devine, Jr.
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K060117
Trade/Device Name: Bovie Button Remote Hand Switch
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 14, 2006
Received: February 15, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060117

Indications for Use

510(k) Number (if known): K060117

Device Name: Bovie Button Remote Hand Switch

Indications for Use:

The **Bovie Button Remote Hand Switch** is intended for use to remotely activate the CUT and COAGULATION modes of an electrosurgical generator to deliver monopolar Radiofrequency current to an endoscopic instrument. The device serves as the connection between the electrosurgical accessory and the generator.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 801 Subpart C)

(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, and Neurological Devices

510(k) Number K060117