K061307

JUL 18 2006

510(k) SUMMARY (per CFR21 807.92(c))

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GENERAL INFORMATION:

510k Owner's Name **Address**	Aaron Medical 7100 30th Avenue North St. Petersburg, Florida 33710-2902
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 384-2323 FAX Number: (727) 347-9144
Date Prepared:	May 8, 2006

DEVICE DESCRIPTION:

Trade Name:	Bovie ina Flash™ Suture Remover
Common Name:	Suture Removal Device
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code GEI) Thermal cautery Unit (21CFR 886.4115; Class II; Product Code HQP) Suture Removal Kit (Unclassified; Product Code MCZ) Gauze/Sponge, Nonresorbable for External Use (21CFR 878.4014; Class I; Product Code NAB) Manual Surgical Instrument for Manual Use (Forcep) (21CFR 878.4800; Class I; Product Code HTD) Surgical Instrument Motors and Accessories /Attachments (Battery Replacement/ Rechargeable) (21CFR 878.4820; Class I; Product Code MOQ)

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510(k) SUMMARY (per CFR21 807.92(c))

DEVICE DESCRIPTION:

Predicate Devices:

Suncoast Medical Manufacturing	**Replace-a-Tip Cautery** **Pyro Tip**	**K840434** **K841591**
Modern Medical	**Battery Powered Cautery**	**K023506**
Busse Hospital Disposables	**Suture Removal Kit**	**Pre-Amendment**
Powertron Medical Devices	**Battery Pack**	**Exempt**
Medline Industries	**Gauze**	**Exempt**
Medline Industries	**Forceps**	**Exempt**

INTENDED USE:

The Bovie inaFlash™ Suture Remover is used to perform suture removal procedures in health care facilities and veterinary offices. The suture removal procedures include those in which the sutures are located externally on the surface of the skin.

DEVICE COMPONENTS AND OPERATION:

The Suture Remover consists of a rechargeable power handle, charging stand, and a sterile, single-use kit distributed in a multipack. The single-use kit includes three components, two of which are Class I devices (forceps and gauze) commonly used in predicate suture removal kits. The forceps and gauze components are substantially equivalent to those included in other Class I, Premarket notification-exempt devices. The single-use tip component is included in the sterile kit. After the handle is charged, the tip is attached to the power handle. The bottom of the tip is placed flat against the sutured skin surface so that the tip filament only touches the suture. The button is pressed, delivering heat to the filament for about 0.5 second prior to deactivating. This process is completed for all sutures, after which the suture threads are easily removed using the supplied forceps. Using a heated filament to cut the suture provides an advantage over the use of scissors to cut the suture because pulling of the suture prior to the cut is minimized.

The suture removal handle and cutting tip use technology substantially equivalent to the Suncoast Medical Replace-A-Tip Cautery (K840434), the Suncoast Medical Pyro Tip (K841591), and the Modern Medical Battery Powered Cautery (K023506). Replaceable tips for all devices are single-use and are activated after pushing a button on the handle. Whereas the predicate devices use replaceable alkaline batteries, the Bovie Suture Cutter handle utilizes a rechargeable battery pack. The Modern Medical Battery Powered Cautery (K023506) was also found substantially equivalent for the use of sculpting (cutting and shaping to fit) woven grafts. These grafts are constructed of polyethylene materials similar to those of suture material.

Electromagnetic Compatibility testing in accordance with EN 60601-1-2 was successfully performed. Hazard analysis evaluations were also performed for the Suture Remover. There are no new hazards presented with the use of the Suture Cutter as compared with predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Aaron Medical
% Mr. Richard Kozloff
Vice President, QA/RA
7100 30th Avenue North
St. Petersburg, Florida 33710-2902

Re: K061307
Trade/Device Name: Bovie Suture Remover
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 8, 2006
Received: May 12, 2006

Dear Mr. Kozloff

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" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K061307

Device Name: Bovie Suture Remover

Indications for Use:

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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)

Marilyn Buchner for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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