K022856

FEB 1 0 2003

510(K) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: IDS 300 High Frequency Electrosurgical Generator
COMMON NAME: Electrosurgical Generator
CLASSIFICATION NAME: Electrosurgical Cutting and Coagulation Devices and Accessories (21 CFR 878.4400)

The **IDS 300 High Frequency Electrosurgical Generator** is a non-sterile, reusable multi-purpose electrosurgical generator for use in the operating arena which features both monopolar and bipolar functions which meet surgical demands for safety, flexibility, reliability, and convenience. Functions which the **IDS 300** performs includes: monopolar cut; monopolar cut with hemostasis (blend); force coagulation; fulguration; and bipolar.

SUBSTANTIAL EQUIVALENCE: The **IDS 300** is substantially equivalent to the Aaron 2100 Electrosurgical Generator (K001382) and the Valleylab Electrosurgical Generator, Model Force FX (K944602) in design, operation, intended use, materials, components, energy source, and performance claims.

TESTING: Testing which has been performed on the **IDS 300** indicates that this device is substantially equivalent in performance and method of operation.

HAZARD ANALYSIS: Hazard analysis evaluations were performed on the **IDS 300.** Test results indicated that there are no new hazards presented with the use of the **IDS 300 High Frequency Electrosurgical Generator** as compared with the predicate devices.

In conclusion, the **IDS 300 High Frequency Electrosurgical Generator** is substantially equivalent to the predicate devices in methods of operation, intended use, and results derived from operation.

Submitted By: Richard A. Kozloff
Vice President, Quality Assurance and Regulatory Affairs
Aaron Medical Industries, a Bovie Company
7100 30th Avenue North
St. Petersburg, FL 33710-2902
(727) 384-2323

Contact Person: Richard A. Kozloff
Date: August 23, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2003

Aaron Medical Industries
Richard A. Kozloff
Vice President, Quality Assurance & Regulatory Affairs
7100 30th Avenue, North
St. Petersburg, Florida 33710-2902

Re: K022856
Trade/Device Name: Bovie IDS-300 High Frequency Electrosurgical Generator
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation devices and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 3, 2002
Received: December 4, 2002

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K022856

Device Name: Bovie IDS 300 High Frequency Electrosurgical Generator

Model: IDS-300

Indications For Use:

The **Bovie IDS 300 High Frequency Electrosurgical Generator** is a non-sterile reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the operating arena.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022856