K110695

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B. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN 28 2011

Aesculap Bipolar High Frequency (HF) Device
June 13, 2011

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT Lisa M. Boyle, Sr. RA Specialist
800-258-1946 x 5274 (phone)
610-791-6882 (fax)
lisa.boyle@aesculap.com

TRADE NAME: Aesculap Bipolar High Frequency (HF) Device

COMMON NAME: Bipolar HF Electrosurgical Unit

CLASS. NAME: Electrosurgical, Cutting & Coagulation & Accessories (GEI)

REG. NUMBER: 878.4400 (Class II)

SUBSTANTIAL EQUIVALENCE

The Aesculap Bipolar HF Device as described in this premarket notification is substantially equivalent to the following predicate devices:

- Aesculap Bipolar Coagulator (K952524)
- Wolf Model 2352 (K945914)
- Valleylabs Force FZ (K953195)
- Valleylabs Forcetriad (K102913)

DEVICE DESCRIPTION

Aesculap's **Bipolar HF Device** is a non-sterile, reusable electrosurgical generator capable of generating high frequency electrical current, driven through a software based program, for coagulation with existing Aesculap bipolar instruments (e.g. forceps). It is equipped with a bipolar outlet. The device is fitted with a universal power adapter for mains voltages 100-120V and 220-240V. All software and electrical components are housed within a combination metallic and thermoplastic enclosure. A bipolar cord connects the instruments to the unit. The unit is activated by means of a foot control.

INDICATIONS FOR USE

Aesculap's Bipolar Coagulator (GN160) is intended for use in surgery to generate electrical power for bipolar instruments. Bipolar coagulators are use in Neurosurgery, ENT surgery, urology, laparoscopy and plastic surgery.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Bipolar HF Device described in this premarket notification share similar features and functions such as intended use, labeling, and basic operating principles to the following predicate devices: Aesculap Bipolar Coagulator (K952524), Wolf Model 2352 (K945914), Valleylabs Force FZ (K953195), and the Valleylabs Forcetriad (K102913).

Testing of the subject device was found to be similar in performance to the previously cleared device with similar indications.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The Aesculap Bipolar HF Device conforms to the following IEC standards:

- IEC 60601-1: Medical electrical equipment – Part 1: General requirement for safety,
- IEC 60601-2-2: Medical electrical equipment – Part 2: Particular requirements for the safety of high frequency surgical equipment,
- IEC 60601-1-2: Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility EMC Requirements and Tests.
- IEC 62304: Medical device software – Software life cycle process

Testing results demonstrate that the Aesculap Bipolar HF Device is safe and effective. No clinical testing was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap, Inc.
% Ms. Lisa M. Boyle
Sr. Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

JUN 28 2011

Re: K110695
Trade/Device Name: Bipolar HF Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 15, 2011
Received: June 16, 2011

Dear Ms. Boyle:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K110695

Device Name: Aesculap Bipolar HF Device

Indications for Use:

Aesculap's Bipolar Coagulator (GN160) is intended for use in surgery to generate electrical power for bipolar instruments. Bipolar coagulators are used in neurosurgery, ENT surgery, urology, laparoscopy, and plastic surgery.

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110695