

**MAY 30 2000**

K001330

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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

in Accordance with SMDA of 1990

**SOVEREIGN™ BIPOLAR INSTRUMENTS**

April 26, 2000

**COMPANY:** Aesculap®, Inc.  
1000 Gateway Blvd.  
So. San Francisco, CA 94080

**CONTACT:** Lia S. Jones, Regulatory Associate  
650-624-5073 (phone)  
650-589-3007 (fax)  
[lia.jones@aesculap.com](mailto:lia.jones@aesculap.com) (email)

**TRADE NAME:** SOVEREIGN™ Bipolar Instruments

**COMMON NAME:** Bipolar Instrument

**DEVICE CLASS:** Class II

**PRODUCT CODE:** GEI

**CLASSIFICATION:** 878.4400  
Electrosurgical cutting and coagulation device and accessories

**REVIEW PANEL:** General & Plastic Surgery

**INTENDED USE**

The Sovereign Bipolar Instruments are intended to facilitate grasping, cutting and manipulation of soft tissue and blood vessels during laparoscopic procedures with the use of high-frequency electrical current (bipolar electrocautery).

**DEVICE DESCRIPTION**

Aesculap's Sovereign Bipolar Instruments are comprised of a variety of non-sterile, reusable endoscopic scissors and forceps. The modular instruments utilize standard bipolar cables (with flat plugs) connected to compatible electrosurgical generators that supply bipolar energy. The instruments may be sterilized by steam sterilization.

**PERFORMANCE DATA**

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The Sovereign Bipolar Instruments, however, conform to the following electromedical standard: IEC 60601-2-18.

**SUBSTANTIAL EQUIVALENCE**

The Sovereign Bipolar Instruments are substantially equivalent in their intended use, material composition, labeling, design and basic operating principles to the following predicate devices:

- Aesculap Bipolar Forceps (K954652)
- Jarit Detach® Bipolar System
- Enable Endoscopic Bipolar Scissors (K992996)
- Valleylab BiSure™ Laparoscopic Bipolar Forceps (K983743)



MAY 3 0 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lia S. Jones  
Regulatory Associate  
Aesculap, Inc.  
1000 Gateway Boulevard  
South San Francisco, California 94080-7028

Re: K001330  
Trade Name: SOVEREIGN Bipolar Instruments  
Regulatory Class: II  
Product Code: GEI  
Dated: April 26, 2000  
Received: April 27, 2000

Dear Ms. Jones:

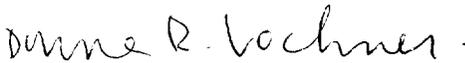
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

