



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

Aesculap Incorporated
Ms. Denise Adams
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

July 21, 2015

Re: K151858

Trade/Device Name: Caiman Seal and Cut Technology
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 6, 2015
Received: July 8, 2015

Dear Ms. Adams:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) SUMMARY (as required by 21 CFR 807.92)****Caiman[®] Seal and Cut Technology**

July 15, 2015

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

CONTACT: Denise R. Adams, RAC
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TRADE NAME: Caiman Seal and Cut Technology

COMMON NAME: Electrosurgical, Cutting & Coagulation & Accessories

CLASSIFICATION NAME: Electrosurgical Cutting and Coagulation Device and Accessories

REGULATION NUMBER: 21 CFR 878.4400

PRODUCT CODE: GEI

SUBSTANTIAL EQUIVALENCE

Caiman Seal and Cut Technology is substantially equivalent to the Caiman Seal and Cut Technology System cleared via K140839.

DEVICE DESCRIPTION

Caiman Seal and Cut Technology consists of the Lektrafuse RF Generator and the sterile, single use Caiman devices. These devices are capable of vessel sealing, blunt dissection, grasping and dividing tissue enclosed within its jaws during open and laparoscopic procedures. The devices are designed to be used with the dedicated Lektrafuse RF Generator and create vessel ligation by the application of bipolar electrical RF energy and tissue division with a cutting blade.



INDICATIONS FOR USE

Caiman Seal and Cut Technology consists of dedicated bipolar electrosurgical instruments intended for use in general surgery and gynecologic surgical procedures where ligation and division of vessels is desired. The instruments create a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structure (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

Instruments 24cm in length are indicated for open procedures and instruments 36cm and 44 cm in length are indicated for laparoscopic procedures. The indications for use include general surgical procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resection, and oophorectomy etc., or any procedure where vessel ligation (seal and cut), tissue grasping, and dissection is performed. The devices can be used on vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

Caiman Seal and Cut Technology has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

TECHNOLOGICAL CHARACTERISTICS (compared to predicate)

The modifications made to the Caiman Seal and Cut Technology system do not affect the fundamental scientific technology. The design, materials, and principal of operation have not changed for these devices. The modifications made to these devices do not raise any new issues of safety and effectiveness.

PERFORMANCE DATA

Bench testing was performed on the modified devices and found them to be substantially equivalent to the predicate devices. The Plus Mode performance verification on the Lektrafuse Generator with the Caiman 12mm and Caiman 5mm included the following tests:

1. Seal Burst Pressure on three different tissue types
2. Visual Arcing
3. Jaw Adhesion
4. Thermal Spread

Caiman Seal and Cut Technology is in compliance with the following safety standards:

1. IEC 60601-2-2
2. IEC 60601-1-2
3. IEC 60601-1: 3rd Edition
4. IEC 62304