



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

July 20, 2015

Re: K151696

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: June 22, 2015
Received: June 23, 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

Indications for Use

510(k) Number (if known)

K151696

Device Name

Caiman Seal and Cut Technology

Indications for Use (Describe)

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 24 cm in length are indicated for open procedures and instruments 36 cm 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY (as required by 21 CFR 807.92)

Caiman[®] Seal and Cut Technology

June 22, 2015

COMPANY:

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

CONTACT:

Denise R. Adams, RAC
610-984-9076 (phone)
610-791-6882 (fax)

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 K130596.

DEVICE DESCRIPTION

Caiman Seal and Cut Technology consists of the Lektrafuse RF Generator and the Caiman seal and cut devices which are provided as sterile, single use 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. The 5 mm instruments (not the generator) are the subject of this submission.

INDICATIONS FOR USE

Caiman Seal and Cut Technology consists of dedicated bipolar electro-surgical 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 electro-surgical 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 24 cm in length are indicated for open procedures and instruments 36 cm 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 predicates)

The modifications made to the Caiman Seal and Cut Technology system do not affect the fundamental scientific technology. The principal of operation has not changed for these devices. The following modifications made to these devices do not raise any new issues of safety and effectiveness: addition of 5mm articulating instrument, addition of a gasket in the shaft, shaft length, isolator assembly, distal cable connector, an adhesive change. Material changes were made to the dissection clip and heat shrink material.

PERFORMANCE DATA

Bench testing was performed on the modified devices and found them to be substantially equivalent to the predicate devices. The testing included the following tests: Articulation Angle/Torque, Biocompatibility, Cutter Advancement, Cutting Blade Termination, Dissection Distance, Distal Jaw Gap, Flow Rate, Force to Lock and Release Jaw, Instrument Life, Jaw Adhesion, Jaw Force (clamping compression), Jaw Grasp, Tissue Resistance Test, Sealing (length, size & time), Seal Burst Pressure on three different tissue types, Thermal Spread Trocar Compatibility, Visual Arcing and Regrasp.

The Caiman Seal and Cut Technology is in compliance with the following safety standards: IEC 60601-2-2, IEC 60601-1-2, IEC 60601-1: 3rd Edition, and IEC 60601-2-18.