APR 2 8 2014

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

Caiman® Seal and Cut Technology

April 25, 2014

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Denise R. Adams 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 Caiman Seal and Cut Technology cleared via K130596.

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.

The Caiman 12 Plus (44cm) and the Caiman 5 are indicated for laparoscopic procedures and the Caiman 12 Plus (24cm) is indicated for open 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 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.

Caiman Seal and Cut Technology is in compliance with the following standards: IEC 60601-1 3rd edition, IEC 60601-1-2:2007, IEC 60601-2-2:2009, and IEC 62304 1st edition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 28, 2014

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

Re: K140839
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: April 1, 2014
Received: April 2, 2014

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,

David Krause -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140839

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.

The Caiman 12 Plus (44cm) and the Caiman 5 are indicated for laparoscopic procedures and the Caiman 12 Plus (24cm) is indicated for open 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."