December 18, 2020

Aesculap Inc.
Omunique Luke
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K203461
Trade/Device Name: Aesculap Caiman 12 Seal and Cut Technology System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 23, 2020
Received: November 24, 2020

Dear Omunique Luke:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203461

Device Name
Aesculap Caiman 12 Seal and Cut Technology System

Indications for Use *(Describe)*

Caiman Seal and Cut Technology System 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 36cm and 44cm in length are indicated for laparoscopic procedures and instruments 24 cm in length are 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 System 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.

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."

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

Caiman 12 Seal and Cut Technology System

December 17, 2020

COMPANY:	Aesculap, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Nikki Luke 484-523-6868 (phone) nikki.luke@aesculapimplants.com 610-791-6882 (fax)

TRADE NAME:	Aesculap® Caiman 12 Seal and Cut Technology System
COMMON NAME:	Electrosurgical, Cutting & Coagulation & Accessories
CLASSIFICATION NAME:	General and Plastic Surgery
REGULATION NUMBER:	21 CFR 878.4400
PRODUCT CODE:	GEI
DEVICE CLASS:	Class II per 21 CFR 878.4400

PREDICATE DEVICE

Caiman Seal and Cut Technology (K130596)

DEVICE DESCRIPTION

The Aesculap® Caiman Seal and Cut Technology System consists of sterile, single-use bipolar instruments that connect to a dedicated bipolar RF generator. The Caiman instruments are designed to grasp, seal (ligate), and mechanically divide (cut) varying lengths of tissue (for example mesentery) per device application. This is accomplished by a two electrode (side by side-top and bottom) design. The instruments are capable of vessel sealing, grasping, and dividing tissue enclosed within its dissection clips.

The reason for this submission is to capture modifications to the caiman 12 (24cm and 44cm) instruments.

INDICATIONS FOR USE

Caiman Seal and Cut Technology System 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 36cm and 44cm in length are indicated for laparoscopic procedures and instruments 24 cm in length are 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 System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

TECHNOLIGICAL CHARACTERISTICS (compared to predicate devices)

The table below provides a summary of the device technological characteristics comparing the subject device and predicate device. The modifications made to these devices do not raise any new issues of safety and effectiveness, as confirmed by the testing and validation activities described in the submission.

	Subject Device: Caiman Seal and Cut Technology System Product Code: GEI K203461	**Predicate Device: Caiman Seal and Cut Technology System Product Code: GEI K130596**	
Intended Use	Caiman Seal and Cut Technology System instruments are intended for use in general surgery and gynecologic surgical procedures where ligation and division of vessels is desired.	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.	Same
Indications for Use	Caiman Seal and Cut Technology System 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 36cm and 44cm in length are indicated for laparoscopic procedures and instruments 24 cm in length are 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	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 (36cm) 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	Same

	as large as will fit in the jaws of the instrument. Caiman Seal and Cut Technology System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.	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.	
Material Composition	**Handle -** molded thermoplastic **Shaft -** stainless steel and molded thermoplastic **Jaw –** stainless steel **Jaw Insulation Components -** PEEK	**Handle -** molded thermoplastic **Shaft -** stainless steel and molded thermoplastic **Jaw –** stainless steel **Jaw Insulation Components -** PEEK	Same
Functional Use	Grasping Ligation and Coagulation	Grasping Ligation and Coagulation	Same
Surgical Approach	Caiman 12 (44cm)-Laparoscopic Caiman 12 (24cm)- Open	Caiman 12 (44cm)-Laparoscopic Caiman 12 (24cm)- Open	Same
Length	24 cm 44 cm	24 cm 44 cm	Same
Jaw	**Upper Jaw Assembly** Stainless-Steel Material: 420 SST (EN ISO 1.4021) Stainless-Steel Material: 304 (EN ISO 1.4301) Electrical Insulation Features: PEEK **Lower Jaw Assembly** Stainless-Steel Material: 17-4 PH (EN ISO 1.4542) Stainless-Steel Material: 304 (EN ISO 1.4301) Electrical Insulation Features: PEEK **Jaw Shape:** Straight	**Upper Jaw Assembly** Stainless-Steel Material: 420 SST (EN ISO 1.4021) Stainless-Steel Material: 304 (EN ISO 1.4301) Electrical Insulation Features: PEEK **Lower Jaw Assembly** Stainless-Steel Material: 17-4 PH (EN ISO 1.4542) Stainless-Steel Material: 304 (EN ISO 1.4301) Electrical Insulation Features: PEEK **Jaw Shape:** Straight	Same

Jaw Clamp Force	Within Specification 170 N - 350 N	Within Specification 170 N - 350 N	Same
Diameter	12mm	12mm	Same
Number of Electrodes (Pairs)	2	2	Same
Electrode Length	5 cm	5 cm	Same
Electrode Width	0.25 cm	0.25 cm	Same
Electrode Texture	Smooth with PEEK stops to maintain consistent gap between electrode surfaces	Smooth with PEEK stops to maintain consistent gap between electrode surfaces	Same
Cable	10ft	10ft	Same
Sterile/Single Use	Yes	Yes	Same
Shelf Life	3 years	3 years	Same

PERFORMANCE TESTING

Non-clinical testing was conducted as part of demonstrating substantial equivalence to the predicate device and ensure the design changes met the predetermined acceptance criteria. A risk analysis was completed to identify the risks associated with the modifications to the Caiman Seal and Cut Technology System. Verification testing was conducted to evaluate the modification. The following tests associated with the device modifications were performed on the subject device according to the methods and acceptance criteria as required per test protocol.

See Design verification table below:

Design verification

Test	Acceptance Criteria	Results
Instrument Cycling Test	No pin walking shall be observed	Pass
Jaw Clamping Force Test	Jaw clamping force must remain within specification 170 N - 350 N	Pass

The testing performed verified and validated that the Caiman 12 Seal and Cut Technology System has met all acceptance criteria.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the modifications described in this submission do not affect the intended use of the device or alter the fundamental scientific technology of the device.