March 12, 2019

Aesculap, Inc.
Ms. Jessica Stigliano
Regulatory Affairs Associate
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K183180
Trade/Device Name: Caiman 5 Maryland
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 8, 2019
Received: February 9, 2019

Dear Ms. Stigliano:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.03.12 13:03:43 -04'00'

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

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 on last page.

510(k) Number *(if known)*
K183180

Device Name
Caiman 5 Maryland

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 12.5 cm, 17 cm, and 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)

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)*

K183180

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

Caiman® 5 Maryland
March 11, 2019

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

CONTACT: Ms. Jessica Stigliano
610-984-9063 (phone)
610-791-6882 (fax)
jessica.stigliano@Aesculapimplants.com

TRADE NAME: Caiman® 5 Maryland

COMMON NAME: Electrosurgical, Cutting & Coagulation & Accessories

REGULATION NUMBER: 21 CFR 878.4400

PRODUCT CODE: GEI

REVIEW PANEL: General and Plastic Surgery

PRIMARY PREDICATE
K151696 – Caiman Seal and Cut Technology

REFERENCE DEVICE
K130596 – Caiman Seal and Cut Technology
K110824 - Aragon Surgical RF System - 5mm Laparoscopic Instrument

SUBSTANTIAL EQUIVALENCE
Aesculap®, Inc. believes that the Caiman® 5 Maryland is substantially equivalent to the primary predicate, Caiman® Seal and Cut Technology (K151696) and reference devices, Caiman® Seal and Cut Technology (K130596) and Aragon Surgical RF System – 5mm Laparoscopic Instrument (K110824).

DEVICE DESCRIPTION

The Caiman® 5 Maryland instruments are 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.

INDICATIONS FOR USE

Instruments 12.5 cm, 17 cm, and 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 Predicate(s))

The modifications made to the Caiman instruments do not affect the fundamental scientific technology. 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.

Attribute	Subject Device Caiman® 5 Maryland	Primary Predicate Caiman Seal and Cut Technology (K151696)	Reference Device Caiman Seal and Cut Technology (K130596)	Reference Device Aragon Surgical RF System Caiman 5 Laparoscopic Instrument (K110824)
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 12.5 cm, 17 cm, and 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,	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,	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	The Aragon Surgical Caiman 5 Laparoscopic Instrument is a dedicated bipolar electrosurgical instrument intended for use in general surgical and gynecologic laparoscopic procedures where ligation and division of vessels is desired. The instrument creates a seal by the application of bipolar electrosurgical RF energy to vascular structures (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue. Indications for use include general laparoscopic procedures, including urologic, vascular, thoracic, and thoracoscopic, and gynecological laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy etc. The Aragon Surgical Caiman 5 Laparoscopic Instrument can be used on vessels up to and including 7mm, and tissue bundles as large as will fit in the jaws of the instrument.

	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.	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.	(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.	The Aragon Surgical Lektrafuse RF System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.
Material Composition	**Handle** - molded thermoplastic **Shaft** - stainless steel **Insulation** - polyester tube (Caiman 5) ETFE (Caiman 5 Articulating) **Dissection clip** - PEEK	**Handle** - molded thermoplastic **Shaft** - stainless steel **Insulation** - polyester tube (Caiman 5) EFTE (Caiman 5 Articulating) **Dissection clip** - Valox HX 420 HP	**Handle** - molded thermoplastic **Shaft** - stainless steel **Insulation** - polyester tube (Caiman 5) **Dissection clip** – PEEK (Caiman 5)	Molded thermoplastic handle, stainless steel shaft
Functional Use	Grasping Ligation and Coagulation **(unchanged)**	Grasping Ligation and Coagulation	Grasping Ligation and Coagulation	Grasping Ligation and Coagulation
Surgical Approach	125mm and 170mm – Open 360mm and 440mm – Laparoscopic **(unchanged)**	240mm - Open 360 and 440mm - Laparoscopic	Caiman 12 Plus (44cm)- Laparoscopic Caiman 12 Plus (24cm)- Open Caiman 5- Laparoscopic	Laparoscopic
Length	125mm 170mm 360mm 440mm	240mm 360mm 440mm	Caiman 12 Plus- 44cm Caiman 12 Plus- 24cm Caiman 5- 36cm	36cm
Jaw Shape	Curved	Straight	Straight	Straight
Diameter	5mm **(unchanged)**	5 mm	Caiman 12 Plus- 12mm	5 mm

			Caiman 5- 5mm	
Articulation	125, 170, 360, and 440mm – non-articulating 360 and 440 - articulating	240, 360, and 440mm – no 360mm - yes	Caiman 12 Plus- yes Caiman 5- no	No
Number of Electrodes (Pairs)	1	1	Caiman 12 Plus- 2 Caiman 5- 1	1
Electrode Length	21.5 cm	2.65 cm	Caiman 12 Plus- 5cm Caiman 5- 2.65cm	2.65 cm
Electrode Width	1.01- 1.63 mm – varies over the length of the jaw due to curve	0.13-0.15 cm	Caiman 12 Plus- 0.25cm Caiman 5- 0.13-0.15cm	0.13-0.15cm
Electrode Texture	Smooth with conductive (steel) and non conductive (Alumina Titania) stop members on the Jaws, to maintain consistent gap between electrode surfaces.	Smooth, with PEEK stop at the distal end of the jaw and Valox stop at the proximal end of the jaw, to maintain consistent gap between electrode surface.	Smooth with PEEK stops to maintain consistent gap between electrode surfaces	Smooth with PEEK stops to maintain consistent gap between electrode surfaces
Cable	10ft **(unchanged)**	10ft	10ft	10ft
Sterile/ Single Use	Yes **(unchanged)**	Yes	Yes	Yes

PERFORMANCE DATA

Design verification

Test	Test Method Study	Results
Tissue-related performance test for arteries	Provide evidence of several technical requirements and a user need. Intended to verify the tissue-related requirements and demonstrate the life cycle for typical applications.	Pass
Burst Pressure testing for veins	Generate burst pressure data for veins of all relevant diameters	Pass
Jaw Tissue stress test	Demonstrate that under load up to and beyond the load limit, the durability of the Maryland instruments is comparable to that of the predicate devices.	Pass
Validation of usability	Validate user needs related to usability through a user survey in order to document the usability, and thus to ensure that the product under investigation meets the requirements for usability in accordance with the applicable standards	Pass

Electrical Safety

The Caiman® 5 Maryland instruments conform to the following electrical safety and EMC standards;

- IEC 60601-2-2 Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-1-2 General requirements for basic safety and essential performance - Collateral standard Electromagnetic compatibility - Requirements and tests
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-18 Particular requirements for the basic safety and essential performance of endoscopic equipment

Biocompatibility

The Caiman® 5 Maryland instruments continue to confirm to ISO 10993-1, "Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

Sterilization

There have been no changes to the sterilization of the Caiman® 5 Maryland instruments since the predicate device has been cleared in K151696. The instruments continue to be provided sterile. Sterilization of the instruments continue to be in accordance with ISO 11137-2 – method 1.

CONCLUSION

The purpose of this 510(k) premarket notification is to gain marketing clearance for the new Caiman® 5 Maryland instruments presented in this submission. Aesculap® believes the new instruments are similar in indications, design / features, components offered, dimensional ranges, and fundamental scientific technology when compared to their predicates.