Not all energy is created equal.

The Caiman portfolio features a wide range of vessel sealing and cutting devices in open and laparoscopic surgery for vessels up to and including 7 mm and bundles as large will fit in the jaws of the instrument. Uniquely designed jaws optimize procedural efficiency with exceptional transection speed, secure tissue manipulation and minimal thermal spread.
Higher Burst Pressure (up to 205%)

Longer Seals (up to 87%)

Reduction in Transection Time (up to 43%)
Caiman® Vessel Sealers
Value Analysis Brief

Caiman's unique jaw design delivers uniform compression with a clean and consistent seal quality, independent of where the vessel is positioned in the jaws.
- **Strong Uniform Compression** is key to creating a confident seal. Compression force in other devices may decline from proximal to distal end, influencing the sealing quality and causing tissue slippage during jaw closure.

![Compression Footprint](image)

<table>
<thead>
<tr>
<th>PSI</th>
<th>Aesculap Caiman 5 (5 mm)</th>
<th>Comparable Product (5 mm)</th>
<th>Comparable Product (10 mm)</th>
<th>Aesculap Caiman 12 (12 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>274</td>
<td>92</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

Products shown actual size
Caiman® Vessel Sealers
Value Analysis Brief

Caiman has the longest jaws on the market for any advanced bipolar or ultrasonic device available, allowing for heightened efficiency in laparoscopic and open procedures.
<table>
<thead>
<tr>
<th>Jaw Length (mm)</th>
<th>Cut Length (mm)</th>
<th>Caiman® 5 Jaw Comparison</th>
<th>Jaw Length (mm)</th>
<th>Cut Length (mm)</th>
<th>Caiman® 12 Jaw Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>26.5</td>
<td>23.5</td>
<td>Caiman® 5</td>
<td>50</td>
<td>47</td>
<td>Caiman® 12</td>
</tr>
<tr>
<td>19.5</td>
<td>17.8</td>
<td>LigaSure® 5 mm Blunt Tip</td>
<td>36</td>
<td>34</td>
<td>LigaSure® Impact</td>
</tr>
<tr>
<td>20</td>
<td>19</td>
<td>Enseal® G2</td>
<td>40</td>
<td>37</td>
<td>Enseal® G2 Super Jaw</td>
</tr>
<tr>
<td>14.2</td>
<td>14.2</td>
<td>Harmonic ACE®+</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>~16</td>
<td>~16</td>
<td>Thunderbeat®</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.7</td>
<td>11.8</td>
<td>HALO PKS™</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All images are 1/1 ratio
Caiman® Vessel Sealers
Value Analysis Brief

Caiman's unique hinged jaw paired with the longest jaws on the market helps provide exceptional transection time.

REDUCTION IN TRANSECTION TIME

UP TO 43%
■ **Tip-First Closure**  
Lower jaw hinge causes the tip of the instrument to close first, capturing tissue and preventing slippage.

■ **Efficient Energy**  
Minimizes tissue damage with less thermal spread than other advanced bipolar devices.
Caiman® Vessel Sealers
Value Analysis Brief

UP TO 51% STRONGER SEAL
Improved Maneuverability
Articulation is offered to improve access to vessels in challenging anatomy. With 80° of articulation, procedures can be completed more efficiently with fewer trocar port changes. Articulation supports perpendicular vessel sealing, which may result in up to 51% greater sealing strength compared to seals created at an angle.\textsuperscript{4}
Caiman® Vessel Sealers
Value Analysis Brief

**Generator**

Caiman instruments are utilized with the Lektrafuse® generator to deliver a proprietary algorithm of energy customized for various tissue types and thicknesses. Equipped with two sealing modes, the Lektrafuse generator features a plug and play mechanism and a small footprint for ease of use and handling.

Caiman generators can be consigned or purchased.
Articulation Paddle

Caiman® 12
Articulating

Articulating, Non-Articulating

Caiman® 5

Rotation Knob

Sealing Cycle Activation
## Caiman® Vessel Sealers

### Value Analysis Brief

#### 5 mm Vessel Sealer Cross Reference Chart

<table>
<thead>
<tr>
<th>Company</th>
<th>Item No.</th>
<th>Description</th>
<th>Diameter</th>
<th>Shaft Length</th>
<th>Seal Length</th>
<th>Cut Length</th>
<th>Shaft Rotation</th>
<th>Tip First Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aesculap</strong></td>
<td>PL738SU/PL739SU</td>
<td>Caiman 5/ Caiman 5 Articulating</td>
<td>5 mm</td>
<td>24 cm</td>
<td>26.5 mm</td>
<td>23.5 mm</td>
<td>360°</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Medtronic</strong></td>
<td>LF1623</td>
<td>LigaSure® 5 mm Blunt Tip</td>
<td>5 mm</td>
<td>23 cm</td>
<td>19.5 mm</td>
<td>17.8 mm</td>
<td>180°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Medtronic</strong></td>
<td>LF1723</td>
<td>LigaSure Maryland</td>
<td>5 mm</td>
<td>23 cm</td>
<td>20 mm</td>
<td>18 mm</td>
<td>350°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Medtronic</strong></td>
<td>LS1520</td>
<td>LigaSure Dolphin Tip</td>
<td>5 mm</td>
<td>20 cm</td>
<td>18 mm</td>
<td>12 mm</td>
<td>179°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Ethicon</strong></td>
<td>NSLG2C14/NSLG2S14/NSLG2C25/NSLG2S25</td>
<td>Enseal® G2 Curved / Straight</td>
<td>5 mm</td>
<td>14 cm/25 cm</td>
<td>20 mm</td>
<td>17 mm</td>
<td>360°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Ethicon</strong></td>
<td>ETRIO-314H/ETRIO-325H</td>
<td>Enseal TRIO</td>
<td>5 mm</td>
<td>14 cm/25 cm</td>
<td>18 mm</td>
<td>15 mm</td>
<td>360°</td>
<td>No</td>
</tr>
</tbody>
</table>

### Caiman 5 – 24 cm Comparison (Open Surgery)

<table>
<thead>
<tr>
<th>Company</th>
<th>Item No.</th>
<th>Description</th>
<th>Diameter</th>
<th>Shaft Length</th>
<th>Seal Length</th>
<th>Cut Length</th>
<th>Shaft Rotation</th>
<th>Tip First Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aesculap</strong></td>
<td>PL740SU/PL741SU</td>
<td>Caiman 5/ Caiman 5 Articulating</td>
<td>5 mm</td>
<td>36 cm</td>
<td>26.5 mm</td>
<td>23.5 mm</td>
<td>360°</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Medtronic</strong></td>
<td>LF1637</td>
<td>LigaSure 5 mm Blunt Tip</td>
<td>5 mm</td>
<td>37 cm</td>
<td>19.5 mm</td>
<td>17.8 mm</td>
<td>180°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Medtronic</strong></td>
<td>LF1737</td>
<td>LigaSure Maryland</td>
<td>5 mm</td>
<td>37 cm</td>
<td>20 mm</td>
<td>18 mm</td>
<td>350°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Medtronic</strong></td>
<td>LS1500</td>
<td>LigaSure Dolphin Tip</td>
<td>5 mm</td>
<td>37 cm</td>
<td>18 mm</td>
<td>12 mm</td>
<td>179°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Ethicon</strong></td>
<td>NSLG2C35/NSLG2S35</td>
<td>Enseal G2 Curved/Straight</td>
<td>5 mm</td>
<td>35 cm</td>
<td>20 mm</td>
<td>17 mm</td>
<td>360°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Ethicon</strong></td>
<td>NSLG2C35A/NSLG2S35A</td>
<td>Enseal G2 Articulating</td>
<td>5 mm</td>
<td>35 cm</td>
<td>20 mm</td>
<td>19 mm</td>
<td>360°</td>
<td>No</td>
</tr>
<tr>
<td><strong>Ethicon</strong></td>
<td>ETRIO-335H</td>
<td>Enseal TRIO</td>
<td>5 mm</td>
<td>35 cm</td>
<td>18 mm</td>
<td>15 mm</td>
<td>160°</td>
<td>No</td>
</tr>
</tbody>
</table>

---

Products shown actual size

LigaSure is a registered trademark of Covidien AG.

EnSeal is a registered trademark of Ethicon Endo-Surgery, Inc.
# 5 mm Vessel Sealer Cross Reference Chart

## Caiman 5 – 44 cm Comparison (Laparoscopic Surgery)

<table>
<thead>
<tr>
<th>Company</th>
<th>Item No.</th>
<th>Description</th>
<th>Diameter</th>
<th>Shaft Length</th>
<th>Seal Length</th>
<th>Cut Length</th>
<th>Shaft Rotation</th>
<th>Tip First Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aesculap</td>
<td>PL742SU</td>
<td>Caiman 5/ Caiman 5 Articulating</td>
<td>5 mm</td>
<td>44 cm</td>
<td>26.5 mm</td>
<td>23.5 mm</td>
<td>360°</td>
<td>Yes</td>
</tr>
<tr>
<td>Medtronic</td>
<td>LF1644</td>
<td>LigaSure® 5 mm Blunt Tip</td>
<td>5 mm</td>
<td>44 cm</td>
<td>19.5 mm</td>
<td>17.8 mm</td>
<td>159°</td>
<td>No</td>
</tr>
<tr>
<td>Medtronic</td>
<td>LF1744</td>
<td>LigaSure Maryland</td>
<td>5 mm</td>
<td>44 cm</td>
<td>20 mm</td>
<td>18 mm</td>
<td>350°</td>
<td>No</td>
</tr>
<tr>
<td>Medtronic</td>
<td>LF5544</td>
<td>LigaSure Advance</td>
<td>5 mm</td>
<td>44 cm</td>
<td>18 mm</td>
<td>15.5 mm</td>
<td>340°</td>
<td>No</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSLG2C45</td>
<td>Enseal® G2 Straight / Curved</td>
<td>5 mm</td>
<td>45 cm</td>
<td>20 mm</td>
<td>19 mm</td>
<td>360°</td>
<td>No</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSLG2C45A</td>
<td>Enseal G2 Articulating</td>
<td>5 mm</td>
<td>45 cm</td>
<td>20 mm</td>
<td>10 mm</td>
<td>360°</td>
<td>No</td>
</tr>
<tr>
<td>Ethicon</td>
<td>ETRIO-345H</td>
<td>Enseal TRIO</td>
<td>5 mm</td>
<td>45 cm</td>
<td>18 mm</td>
<td>15 mm</td>
<td>360°</td>
<td>No</td>
</tr>
</tbody>
</table>

## 12 mm Vessel Sealer Cross Reference Chart

### Caiman 12 – 24 cm Comparison (Open Surgery)

<table>
<thead>
<tr>
<th>Company</th>
<th>Item No.</th>
<th>Description</th>
<th>Diameter</th>
<th>Shaft Length</th>
<th>Seal Length</th>
<th>Cut Length</th>
<th>Shaft Rotation</th>
<th>Tip First Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aesculap</td>
<td>PL730SU</td>
<td>Caiman 12 Articulating</td>
<td>12 mm</td>
<td>24 cm</td>
<td>50 mm</td>
<td>47 mm</td>
<td>300°</td>
<td>Yes</td>
</tr>
<tr>
<td>Medtronic</td>
<td>LF4318</td>
<td>LigaSure Impact</td>
<td>13.5 mm  (oval)</td>
<td>18 cm</td>
<td>36 mm</td>
<td>34 mm</td>
<td>180°</td>
<td>No</td>
</tr>
<tr>
<td>Medtronic</td>
<td>LS1020</td>
<td>LigaSure Atlas</td>
<td>10 mm</td>
<td>20 cm</td>
<td>22 mm</td>
<td>20 mm</td>
<td>359°</td>
<td>No</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSEALX22L</td>
<td>Enseal G2 Super Jaw</td>
<td>12 mm</td>
<td>20 cm</td>
<td>40 mm</td>
<td>37 mm</td>
<td>360°</td>
<td>No</td>
</tr>
</tbody>
</table>

### Caiman 12 – 44 cm Comparison (Laparoscopic Surgery)

<table>
<thead>
<tr>
<th>Company</th>
<th>Item No.</th>
<th>Description</th>
<th>Diameter</th>
<th>Shaft Length</th>
<th>Seal Length</th>
<th>Cut Length</th>
<th>Shaft Rotation</th>
<th>Tip First Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aesculap</td>
<td>PL731SU</td>
<td>Caiman 12 Articulating</td>
<td>12 mm</td>
<td>44 cm</td>
<td>50 mm</td>
<td>47 mm</td>
<td>300°</td>
<td>Yes</td>
</tr>
<tr>
<td>Medtronic</td>
<td>LS1037</td>
<td>LigaSure Atlas</td>
<td>10 mm</td>
<td>37 cm</td>
<td>22 mm</td>
<td>22 mm</td>
<td>359°</td>
<td>No</td>
</tr>
</tbody>
</table>

All images are 1/4 ratio
## Caiman® Vessel Sealers
### Value Analysis Brief

### Ordering Information

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Shaft diameter</th>
<th>Working length</th>
<th>Quantity per box</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Caiman 5 Non Articulating</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PL738SU</td>
<td>5 mm</td>
<td>24 cm</td>
<td>6</td>
</tr>
<tr>
<td>PL740SU</td>
<td>5 mm</td>
<td>36 cm</td>
<td>6</td>
</tr>
<tr>
<td>PL742SU</td>
<td>5 mm</td>
<td>44 cm</td>
<td>6</td>
</tr>
<tr>
<td><strong>Caiman 5 Articulating</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PL739SU</td>
<td>5 mm</td>
<td>24 cm</td>
<td>6</td>
</tr>
<tr>
<td>PL741SU</td>
<td>5 mm</td>
<td>36 cm</td>
<td>6</td>
</tr>
<tr>
<td>PL743SU</td>
<td>5 mm</td>
<td>44 cm</td>
<td>6</td>
</tr>
<tr>
<td><strong>Caiman 12 Articulating</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PL730SU</td>
<td>12 mm</td>
<td>24 cm</td>
<td>3</td>
</tr>
<tr>
<td>PL731SU</td>
<td>12 mm</td>
<td>44 cm</td>
<td>3</td>
</tr>
</tbody>
</table>

### References

1. Data on file; Caiman® 5, Harmonic Ace®+, Harmonic Ace®+7, LigaSure™ Blunt Tip and Enseal® G2 studied via in vivo vessel sealing and ex vivo burst pressure testing on porcine veins (10 per device) and arteries (10 per device) up to 7mm diameter, 2014

2. Data on file; Caiman® 5, Harmonic Ace®, LigaSure™ Blunt Tip, Enseal® G2, Thunderbeat® and HALO PKS™ sealing length comparison

3. Data on file; Caiman® 5, Harmonic Ace®+, Harmonic Ace®+7, LigaSure™ Blunt Tip and Enseal® G2 studied via in vivo timed transection of porcine colonic mesentery in 15 cm increments (10 per device), 2014

Stocking Request Form

I am requesting the following instruments to be evaluated at our facility:
- PL738SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- PL740SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- PL742SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- PL739SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- PL741SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- PL743SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- PL730SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 24 cm length
- PL731SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 44 cm length

I am requesting Caiman for the following procedures:

Currently, I am using the following energy device(s):
- LigaSure® (Metronic)
- Thunderbeat® (Olympus)
- Enseal® (Ethicon)
- Harmonic® (Ethicon)
- Other ____________

I have clinically evaluated Caiman for the procedures, and below are the results compared to what I am currently using:

<table>
<thead>
<tr>
<th>Key Evaluated Performance Areas</th>
<th>Below Average</th>
<th>Same</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Seal (consistency, hemostasis)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seal &amp; Cutting Length</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tissue Retention in Jaws</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time Saved</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–10 minutes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10–30 minutes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30+ minutes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature: ___________________________  Date: ___________________________

Additional Comments:

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
Evaluation Request Form

I am requesting the following instruments to be evaluated at our facility:

- PL738SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- PL740SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- PL742SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- PL739SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- PL741SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- PL743SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- PL730SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 24 cm length
- PL731SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 44 cm length

I would like to have access to Caiman for the following procedures:

Caiman Technology Offers:

- Tip-First Closure and Hinged Jaw to support tissue retention and uniform compression for delivery of a clean and consistent seal
- Long Jaws for heightened procedural efficiency
  - Seal up to 26.5 mm and cut up to 23.5 mm of tissue at a time (Caiman 5 mm devices)
  - Seal up to 50 mm and cut up to 47 mm of tissue at a time (Caiman 12 mm devices)
- Articulation to improve access to challenging anatomy

Signature: ___________________________  Date: ___________________________  

Additional Comments:

________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________
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 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.

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.

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
               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 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
Indications for Use

**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)**

- [x] 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
PRASStaff@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."