April 12, 2018

STERIS Corporation
Tony Piotrkowski
Senior Regulatory Affairs Manager
5976 Heisley Road
Mentor, OH 44060

Re: K180689
Trade/Device Name: Padlock Clip defect closure device; Padlock Clip Pro-Select defect closure device
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: March 14, 2018
Received: March 15, 2018

Dear Tony Piotrkowski:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K180689

Device Name

Padlock Clip defect closure device
Padlock Clip Pro-Select defect closure device

Indications for Use *(Describe)*

The Padlock Clip™ is indicated for use in flexible Endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of the gastrointestinal organs.

The Padlock Clip™ is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of:

- Endoscopic marking of lesions
- Hemostasis for:
  - o Mucosal/Submucosal defects
  - o Bleeding Ulcers
  - o Arteries <2mm
  - o Polyps <1.5cm in diameter
  - o Diverticula in the Colon
- Closure of GI tract luminal perforations <20mm that can be treated conservatively

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.***

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STERIS®

# 510(k) Summary
# For
# Padlock Clip Pro-Select™ defect closure device and Padlock Clip™ defect closure device

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Anthony Piotrkowski
Senior Regulatory Affairs Manager
Tel: 440-392-7458
Fax: 440-357-9198
Email: tony_piotrkowski@steris.com

Summary Date: April 11, 2018

Premarket Notification Number: K180689

**K180689 STERIS Special 510(k) PREMARKET NOTIFICATION**
**Modification to Padlock Clip and Padlock Clip Pro-Select defect closure devices**

## 1. Device Name

| | |
|---|---|
| Trade Name: | Padlock Clip defect closure device<br>Padlock Clip Pro-Select defect closure device |
| Device Classification: | Class II |
| Common/usual Name: | Ligator clip |
| Classification Name: | Hemorrhoidal ligator |
| Classification Number: | 21 CFR 876.4400 |
| Product Code: | PKL |

## 2. Predicate Device

K120814 Aponos Medical, Padlock Clip

## 3. Description of Device

The Padlock Clip™ ligation clip consists of a preloaded, radiopaque, single use, coin sized ligation clip made of superelastic shape memory alloy for tissue approximation with opening sizes of 6 to 24mm on a flexible delivery system.

## 4. Intended Use

The Padlock Clip™ is indicated for use in flexible Endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of the gastrointestinal organs.

The Padlock Clip™ is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of:

- Endoscopic marking of lesions
- Hemostasis for:
  - Mucosal/Submucosal defects
  - Bleeding Ulcers
  - Arteries <2mm
  - Polyps <1.5cm in diameter
  - Diverticula in the Colon
- Closure of GI tract luminal perforations <20mm that can be treated conservatively

## 5. Description of Technological Similarities and Differences

The Padlock Clip™ is identical to the predicate device except for the specific modification described in this submission. The differences between the proposed and predicate devices are limited to the addition of an alternate supplier for the stainless steel, PTFE-coated stainless steel and black fluorocarbon components of the device and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

### Device Comparison Table

**Table 5-1.** Processor Device Comparison Table

| Feature | Proposed Padlock Clip | K120814 Aponos Padlock Clip | Comparison |
|---|---|---|---|
| **Indications for Use** | The Padlock Clip™ is indicated for use in flexible Endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of the gastrointestinal organs.<br><br>The Padlock Clip™ is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of:<br>• Endoscopic marking of lesions<br>• Hemostasis for:<br>o Mucosal/Submucosal defects<br>o Bleeding Ulcers<br>o Arteries <2mm<br>o Polyps <1.5cm in diameter<br>o Diverticula in the Colon<br>• Closure of GI tract luminal perforations <20mm that can be treated conservatively | The **Aponos Medical** Padlock Clip™ is indicated for use in flexible Endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of the gastrointestinal organs.<br><br>The Padlock Clip™ is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of:<br>• Endoscopic marking of lesions<br>• Hemostasis for:<br>o Mucosal/Submucosal defects<br>o Bleeding Ulcers<br>o Arteries <2mm<br>o Polyps <1.5cm in diameter<br>o Diverticula in the Colon<br>o Closure of GI tract luminal perforations <20mm that can be treated conservatively | Identical<br><br>Removed Aponos Medical from the Indications since the device was purchased by STERIS Corporation |

**K180689 STERIS Special 510(k) PREMARKET NOTIFICATION**
**Modification to Padlock Clip and Padlock Clip Pro-Select defect closure devices**

| Feature | Proposed Padlock Clip | K120814 Aponos Padlock Clip | Comparison |
|---|---|---|---|
| **Operating Principles/ Technology** | The Padlock Clip™ defect closure device is mounted and secured at the distal tip on the outside surface of a flexible endoscope. The Padlock Clip™ is deployed using an independent hand control. The linking cable to the hand control is not located within the endoscopic accessory channel. The Padlock Clip™ delivery system includes a central "tissue chamber" that resides on the distal tip of the endoscope. Clinically efficacious tissue manipulation techniques may be used to pull target tissue into this "tissue chamber" to approximate a larger volume of tissue than would otherwise be approximated by deploying the clip alone. The Padlock Clip™ delivery system is compatible with flexible endoscopes with distal tip outer diameters ranging from 9.5mm to 14mm. | The Padlock Clip™ defect closure device is mounted and secured at the distal tip on the outside surface of a flexible endoscope. The Padlock Clip™ is deployed using an independent hand control. The linking cable to the hand control is not located within the endoscopic accessory channel. The Padlock Clip™ delivery system includes a central "tissue chamber" that resides on the distal tip of the endoscope. Clinically efficacious tissue manipulation techniques may be used to pull target tissue into this "tissue chamber" to approximate a larger volume of tissue than would otherwise be approximated by deploying the clip alone. The Padlock Clip™ delivery system is compatible with flexible endoscopes with distal tip outer diameters ranging from 9.5mm to 14mm. | Identical |
| **Clip** | Radiopaque, single use, coin sized clip made of superelastic shape memory alloy (Nitinol®) | Radiopaque, single use, coin sized clip made of superelastic shape memory alloy (Nitinol®) | Identical |
| **Housing** | Polypropylene | Polypropylene | Identical |
| **Stainless Steel** | Type 304<br>Type 302<br>Type 303<br>Type 18-2 | Type 304<br>Type 302<br>Type 303<br>Type 18-2 | Same grade of steel different supplier |
| **Securing strap** | Black fluorocarbon | Black fluorocarbon | Same material different supplier |
| **Usage** | Single Use | Single Use | Identical |
| **Sterility** | EO Sterilization | EO Sterilization | Identical |
| **Shelf Life** | 2 years | 2 years | Identical |

**Table 5-2** summarizes the verification activity that was performed with its respective acceptance criteria to ensure that this modification does not affect the safety or effectiveness of the Padlock Clip defect closure device.

**Table 5-2.** Summary of verification activities.

| Test | Acceptance Criteria | Result |
|---|---|---|
| Cytotoxicity | Per ISO 10993-5 | Pass |
| Sensitization | Per ISO 10993-10 | Pass |
| Irritation | Per ISO 10993-10 | Pass |
| Acute Systemic Toxicity | Per ISO 10993-11 | Pass |
| Pyrogenicity | Per ISO 10993-11 | Pass |
| Functional Testing | Deploys | Pass |
| | Secures defect | Pass |
| Component Tensile Strength | Meets specification | Pass |
| Component Compressive Strength | Meets specification | Pass |

## 6. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as the legally marketed predicate device (K120814), Class II (21 CFR 876.4400), product code PKL.