March 12, 2026

Taurus Endoscopy
Mariel Bolhouse
Co-founder and CEO
1 Place de l'Hôpital, Bat. IHU
67000 Strasbourg France

Re: K253734
Trade/Device Name: Taurus Clip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: February 9, 2026
Received: February 9, 2026

Dear Mariel Bolhouse:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SIVAKAMI VENKATACHALAM -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253734

Please provide the device trade name(s).

Taurus Clip

Please provide your Indications for Use below.

The Taurus Clip is indicated for placement within the Gastrointestinal (GI) tract of adult patients for the purpose of:
1. Endoscopic marking
2. Hemostasis for:
 - Mucosal/sub-mucosal defects < 3 cm
 - Bleeding ulcers
 - Arteries < 2 mm
 - Polyps < 1.5 cm in diameter
 - Diverticula in the colon
 - Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel and anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus
4. As a supplemental closure method of luminal perforations < 20 mm that can be treated conservatively.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

Taurus Endoscopy
1 Place de l'Hôpital, Bat. IHU
67000 Strasbourg, France

Contact Person: Mariel Bolhouse
Co-founder and CEO
Taurus Endoscopy
Mariel@taurusendo.com

Date Summary Prepared: November 24, 2025

II. DEVICE

Trade Name:	Taurus® Clip
Classification Name:	Hemorrhoidal Ligator
Device Name:	Hemostatic Metal Clip for the GI Tract
Classification Number:	21 CFR §876.4400
Product Code:	PKL
Device Class:	Class II

III. LEGALLY MARKETED PREDICATE DEVICE

Predicate Device:

Trade Name:	Resolution Clip Platform
Manufacturer:	Boston Scientific
510(k) Number:	K222503
Classification Number:	21 CFR §876.4400
Product Code:	PKL
Device Class:	Class II

Reference Device:

Trade Name:	Padlock Clip
Manufacturer:	Steris
510(k) Number:	K192722
Classification Number:	21 CFR §876.4400
Product Code:	PKL
Device Class:	Class II

IV. DEVICE DESCRIPTION

The Taurus Clip is a sterile, single-use endoscopic clip designed for closure, hemostasis, endoscopic marking, and anchoring. The Taurus Clip is designed to be compatible with forward-viewing endoscopes with working channels equal to or greater than 2.8mm.

The Taurus Clip Device consists of two main components: one preloaded titanium Clip Implant and a flexible delivery system, referred to as the "Applier".

The Clip Implant can be used to manipulate the mucosal tissue of the GI tract as desired and then applied (deformed and released) with the handle once in place. The Applier is removed after clip deployment.

V. INTENDED USE/ INDICATIONS FOR USE

The Taurus Clip is indicated for placement within the Gastrointestinal (GI) tract of adult patients for the purpose of:

1. Endoscopic marking
2. Hemostasis for:
   - Mucosal/sub-mucosal defects < 3 cm
   - Bleeding ulcers
   - Arteries < 2 mm
   - Polyps < 1.5 cm in diameter
   - Diverticula in the colon
   - Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel; and

   Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus

4. As a supplemental closure method of luminal perforations < 20 mm that can be treated conservatively

VI. TECHNICAL CHARACTERISTICS

The proposed Taurus Clip has identical Intended Use, Indications for Use, working length, principle of operation, patient population, system configuration, and utilizes the same endoscopic working channel as the predicate Resolution Clip Platform cleared under K222503. The proposed Taurus Clip has a jaw opening width that falls within the range of the predicate device, and both the subject and predicate devices are single-use and sterilized with Ethylene Oxide. The proposed Taurus Clip has a different clip geometry and longer teeth as compared to the predicate device; however, the length of the teeth of the subject device is shorter than the reference device, Padlock Clip Defect Closure System (K192722).

VII. SUBSTANTIAL EQUIVALENCE

The proposed Taurus Clip is substantially equivalent to the currently cleared predicate Resolution Clip Platform (K222503). The technological differences in clip geometry do not raise new or different questions of safety and effectiveness.

VIII. PERFORMANCE DATA

The proposed Taurus Clip meets the requirements of ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*, ISO 11135-1 *Sterilization of Health Care products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routing Control of Sterilization Process for Medical Devices*, and ISO 10993-7 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.*

The following testing was conducted on the proposed Taurus Clip device:

Test	Results
Visual Assessment (device)	Meets Predetermined acceptance criteria
Dimensional Measurements	Meets Predetermined acceptance criteria
Clip Compression Force	Meets Predetermined acceptance criteria
Clip Retention	Meets Predetermined acceptance criteria
Measurement of Retroflexion Angles	Meets Predetermined acceptance criteria
Clip Rotation	Meets Predetermined acceptance criteria
Simulated Use Assessment	Meets Predetermined acceptance criteria
Clip Back Bending	Meets Predetermined acceptance criteria
Applier Buckling Test	Meets Predetermined acceptance criteria
Clip Approach Vertical Oblique	Meets Predetermined acceptance criteria
Full Length Firing Force	Meets Predetermined acceptance criteria
Clip Opening Force	Meets Predetermined acceptance criteria
Design Validation Assessment	Meets Predetermined acceptance criteria

In addition, the proposed Taurus Clip was evaluated for Magnetic Resonance (MR) to support MR Conditionality. The results from the test data demonstrate that the proposed Taurus Clip is an MR Conditional device.

IX. CONCLUSION

Based on the comparison of intended use, indications for use, technological characteristics, non-clinical performance data, and principle of operation, the subject device is as safe, as effective, and performs at least as well as the legally marketed predicate device K222503, Class II (21 CFR 876.4400), product code PKL.