August 26, 2024

Ovesco Endoscopy AG
% Amko Groeneveld
Senior Consultant
novineon CRO GmbH
Friedrich-Miescher-Strasse 9
Tuebingen, 72076
Germany

Re: K241858
Trade/Device Name: BARS Set (100.60)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: June 27, 2024
Received: June 27, 2024

Dear Amko Groeneveld:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Anthony Lee -S

Anthony Lee, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241858

Device Name

BARS Set (100.60)

Indications for Use *(Describe)*

The BARS Set is indicated for clip placement within the context of flexible endoscopy in the GI tract for the purpose of:

- Hemostasis for:
  - Mucosal/submucosal defects < 3 cm
  - Arteries < 2 mm
- Treatment of luminal perforations (< 20 mm) and / or anastomoses (< 50 mm)
- Lumen reduction

NOTE: The BARS Set is not indicated for stent fixation. For stent fixation, use the stentfix OTSC System Set.

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.

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510(k) #:

510(k) Summary

Prepared on: 2024-08-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ovesco Endoscopy AG
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Applicant Contact Telephone	+49707196528154
Applicant Contact	Mr. Antonio Caputo
Applicant Contact Email	antonio.caputo@ovesco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BARS Set (100.60)
Common Name	Hemostatic Metal Clip for the GI Tract
Classification Name	Hemorrhoidal ligator
Regulation Number	876.4400
Product Code(s)	PKL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K101428	OTSC System Set	PKL

Device Description Summary

21 CFR 807.92(a)(4)

Device Description - Explanation of how the device functions:
The subject device constitutes an over-the-scope clip application device used within the context of flexible endoscopy in the gastrointestinal tract. The over-the-scope clip application capabilities center around a memory-shape alloy clip mounted on a transparent plastic cap. Cap (and clip) are mounted on the distal end of an endoscope. Endoscopic instruments are provided in the BARS Set to facilitate insertion and for mobilization and retraction of target tissue into the cap lumen. With the target tissue inside the cap lumen, the memory-shape alloy clip is applied onto the target tissue using a thread mechanism. Contents of the BARS Set are:
- BARS (readily assembled unit of memory-shape alloy clip, transparent plastic cap, thread deployment components, working channels, and guide elements)
- Endoscopic instruments (BARS Anchor silver, BARS Anchor black, Insertion Balloon, Space Keeper Balloon, Guide Wire)

Scientific Concepts forming the basis for the device:
Established memory-shape alloy clips used for over-the-scope clip in flexible endoscopy in the gastrointestinal tract.

Significant Physical and Performance Characteristics:
- Device Design:

Device design is guided by compatibility with flexible endoscopes and device influence on endoscopic functions, e.g., vision and maneuverability.

- Material Used:
Materials used need to be sufficiently biocompatible considering the duration and nature of contact to the human body.

- Physical Properties:
Dimensions need to allow insertion via flexible endoscope into the gastrointestinal tract.

-Reference Devices:
K200684: gastroduodenal FTRD Set
K170867: FTRD System Set
K183309: stentfix OTSC System Set

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The BARS Set is indicated for clip placement within the context of flexible endoscopy in the GI tract for the purpose of:
- Hemostasis for:
  - Mucosal/submucosal defects < 3 cm
  - Arteries < 2 mm
- Treatment of luminal perforations (< 20 mm) and / or anastomoses (< 50 mm)
- Lumen reduction

NOTE: The BARS Set is not indicated for stent fixation. For stent fixation, use the stentfix OTSC System Set.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use differ slightly in specification. These are found to not raise different questions of safety and effectiveness (decision making flowchart point 4). Methods for investigating differences effects on safety and effectiveness are applied. Data from these methods support substantial equivalence.

Technological Comparison

21 CFR 807.92(a)(6)

Technological comparison shows that the subject device and the predicate device, as well as leveraged reference devices share common technological aspects. I.e., all are caps that are attached to an endoscope tip for the purpose of clip application in the gastrointestinal tract. In each case, a thread and hand wheel mechanism is applied for clip application. For the subject device, an application ring is present which is not present in the predicate device. However, reference devices illustrate that presence of an application ring is established for these clip bearing cap devices. The subject device also provides additional working channels that have an established use in endoscopy of the GI-tract.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The sponsor manufactures a number of devices similar to the subject device. Some are leveraged as reference devices. Performance bench testing settings investigated key aspects of device safety and effectiveness. As these performance bench testing settings were largely applied to the reference devices, these tests are considered to be acceptable (510(k) Flowchart decision 5a). Data from these acceptable methods support and demonstrate substantial equivalence (510(k) Flowchart decision 5b).

Device was tested for functional capability and robustness, endoscope compatibility, clip application force, application ring strength, space keeper balloon capability and robustness, usability, and MRI suitability.

Not applicable - no clinical testing submitted for demonstration of substantial equivalence.

The subject device was subjected to performance bench testing previously applied to other devices that constitute a cap attached to an endoscope tip for gastrointestinal clip application. The established precedent from these devices were met as evidenced by application of acceptance criteria and / or comparison to their respective performance bench testing results, thus indicating substantial equivalence.