December 18, 2025

Ovesco Endoscopy AG
℅ Natalja Klymov
Senior Consultant
Novineon CRO GmbH
Friedrich-Miescher-Strasse 9
Tuebingen, Baden-Wuerttemberg 72076
Germany

Re: K251562
Trade/Device Name: OTSCneo System Set (100.03n-14n, 100.27n-31n)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: November 18, 2025
Received: November 18, 2025

Dear Natalja Klymov:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP) – Version 04. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

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.	K251562

Please provide the device trade name(s).

OTSCneo System Set (100.03n-14n, 100.27n-31n)

Please provide your Indications for Use below.

- Instrument for flexible endoscopy and for compression of tissue in the gastrointestinal (GI) tract, for hemostasis or for treating gastrointestinal organ wall lesions. Marking of lesions.
- The OTSCneo clip is indicated for clip placement within the GI tract for the purpose of:
  - Endoscopic marking
- Hemostasis for:
  - Mucosal/submucosal defects < 3 cm
  - Bleeding ulcers
  - Arteries < 2 mm
  - Polyps < 1.5 cm in diameter
  - Diverticuli in the colon
- Closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

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

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

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

510(k) #: K251562

510(k) Summary

Prepared on: 2025-12-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ovesco Endoscopy AG
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Applicant Contact	Mr. Christoph Mielke
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Correspondent Contact Telephone	+49707198979202
Correspondent Contact	Dr. Natalja Klymov
Correspondent Contact Email	natalja.klymov@novineon.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OTSCneo System Set (100.03n-14n, 100.27n-31n)
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
K101482	OTSC System Set	PKL
K183309	stentfix OTSC System Set	PKL
K241858	BARS Set	PKL

Device Description Summary

21 CFR 807.92(a)(4)

DEVICE DESCRIPTION SUMMARY - Explanation 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 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 or suction are used via endoscope working channels 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 manual thread mechanism.

Contents of the OTSCneo System Set are:
- Application cap (with spout, application ring, thread, clip mounted on the cap)
- Hand Wheel
- Thread Retriever

In line with cleared indications, clip application with the subject device can be used for hemostasis, treatment of lesions, or marking of lesions in the GI tract.

SCIENTIFIC CONCEPTS FORMING THE BASIS FOR THE DEVICE:
Established memory-shape alloy clips used for over-the-scope clip application in flexible endoscopy in the gastrointestinal tract.

SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS:
- Device Design:
Device design is guided by compatibility with flexible endoscopes and suitability for endoscopic clip application with the device
- 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.

PREDETERMINED CHANGE CONTROL PLAN
The predetermined change control plan (PCCP) for the device specifies an anticipated addition of a device size variant. The PCCP also specifies the methods to implement the modification so that the device remains as safe and as effective as the predicate device. The following provides an overview of the testing methods and validation activities associated with the proposed change:

PCCP – Planned Modification:
Addition of a smaller device size

PCCP – Test Methods and Validation Activities:
Performance bench testing will be repeated where changed components are concerned. Performance bench testing includes endoscope compatibility, application forces, and evaluation of mechanical properties of components under consideration of pre-determined acceptance criteria.

PCCP – Communication to users:
The current, pre-implementation instructions for use acknowledges the authorized PCCP and the anticipated addition of a device variant.
Labelling will be updated in accordance with the authorized PCCP to provide users with current information on the then added device variant. This includes changes to the instructions for use and labeling on device packaging.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

- Instrument for flexible endoscopy and for compression of tissue in the gastrointestinal (GI) tract, for hemostasis or for treating gastrointestinal organ wall lesions. Marking of lesions.
- The OTSCneo clip is indicated for clip placement within the GI tract for the purpose of:
  - Endoscopic marking
- Hemostasis for:
  - Mucosal/submucosal defects < 3 cm
  - Bleeding ulcers
  - Arteries < 2 mm
  - Polyps < 1.5 cm in diameter
  - Diverticuli in the colon
- Closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

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Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed predicate is found to be legally marketed (decision making point 1).
The proposed predicate device and the subject device are found to have the same intended use (decision point 2).

Technological Comparison

21 CFR 807.92(a)(6)

Differences in technical characteristics are identified (decision point 3). Questions of safety and effectiveness associated with these differences are shown to equally apply to the predicate device. The identified differences do therefore not raise different questions of safety and effectiveness (decision point 4).
Methods for investigating differences effects on safety and effectiveness are applied and include for example endoscope compatibility, application forces, and evaluation of mechanical properties of components (decision point 5a). Data from these methods support substantial equivalence (decision point 5b).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

NON-CLINICAL TESTING:
Submitted non-clinical tests evaluated key device performance characteristics. Performance bench testing items established relevant aspects of the subject device. The described performance bench testing items are equally relevant to the predicate device or reference device as indicated and include endoscope compatibility, evaluation of application forces, and determination of mechanical properties. The data generated from performance bench testing support substantial equivalence.

CLINICAL TESTING:
Not applicable.

SUMMARY & CONCLUSION:
While technical differences were identified, performance bench testing data supports claims of substantial equivalence. Differences usually have precedent in other cleared, reference devices. Substantially, the subject device and the predicate device constitute transparent clip bearing caps with silicon spouts that fit to endoscope tips that incorporate a manual, thread-based application mechanism.