



February 13, 2026

Endo Tools Therapeutics S.A.
Marine Rouyer
Regulatory and Quality Director
Rue Clément Ader, 10
Gosselies, 6041
Belgium

Re: K252400

Trade/Device Name: Endomina EZFuse system
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCW
Dated: January 12, 2026
Received: January 12, 2026

Dear Marine Rouyer:

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.

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,

ANTHONY LEE -S

Anthony C. Lee Ph.D., M.B.A.
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

Submission Number (if known)

K252400

Device Name

Endomina EZFuse system

Indications for Use (Describe)

The endomina® EZFuse system is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract.

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) SUMMARY

Endo Tools Therapeutics' endomina® EZFuse system

In accordance with 21 CFR 807.92 of Federal code of Regulations, the following 510(k) summary is submitted for endomina® EZFuse system.

The endomina® EZFuse system is composed of endomina® platform and endomina® EZFuse suture.

The endomina® platform is a short-term, single-use platform providing additional therapeutic channels for a flexible endoscope to be used in surgical endoscopy in the gastrointestinal tract consisting of a bracket that closes around the endoscope, a tubing system and a handle.

The endomina® EZFuse suture is a device composed of two parts: one suture chain and one delivery device. The suture chain (implantable) is loaded into the delivery device (not implantable).



Submitter Name & Address Endo Tools Therapeutics S.A.
Rue Clément Ader, 10
6041 Gosselies
Belgium

Contact Person Marine ROUYER
Regulatory and Quality Director
regulatory@endotools.be
Phone: +32 71 91 94 09

Date: January 28, 2026

510(k) Number: K252400

Device identification

Trade Device Name: endomina® EZFuse system

FDA Product Code: OCW

Classification Name: Endoscope and accessories

Regulation Number: 21 CFR 876.1500

Regulatory Class: Class II

Predicate Device: K211309 – endomina® system (Endo Tools Therapeutics S.A.)

Device Description: The endomina® EZFuse system is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract utilizing an endoscope. The system is comprised of a triangulation platform (endomina® platform) and an instrument for tissue piercing and approximation (endomina® EZFuse delivery system and suture). The endomina® EZFuse system is sterile packaged and designed for single use and is manufactured from various thermoplastic, stainless steel materials, biocompatible 3D printing materials and other medical grade materials.

endomina® platform:
The endomina® platform can be assembled on a regular flexible endoscope inside the gastrointestinal tract. It includes a bendable therapeutic channel meant for the endoscopic tool endomina® EZFuse suture. This channel can be deployed perpendicular to the axis of the endoscope, thereby ensuring the triangulation, leaving the channel of the endoscope free for other instruments.



endomina® EZFuse suture:

Endomina® EZFuse suture is an instrument intended to be used with the endomina® platform and a flexible endoscope for tissue approximation in the gastrointestinal. It is inserted in the bendable arm of endomina®'s platform. It enables piercing and approximation of two, internal tissues with a needle which are then linked by releasing anchors connected with suture. These anchors create a stitch that can then be tightened, generating interrupted stitches in the gastrointestinal tract.

Indications for Use:

The endomina® EZFuse system is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract.

Technological Characteristics

Product Characteristics		endomina® system	endomina® EZFuse system
Intended use			
510(k) Clearance		K211309	K252400
Area		Gastrointestinal tract	
Indications for Use		The endomina® system, composed of a triangulation platform (endomina® platform) and an instrument for tissue piercing and approximation (TAPES), is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract. The system is to be used on an adult population.	The endomina® EZFuse system is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract.
Intended use		Endoscopic placement of suture(s) and approximation of soft tissue.	
Technological characteristics			
Single use		Yes	
Sterilization		Terminally sterilized to SAL 10 ⁻⁶ using a validated EO method	
Shelf-Life Claim		2 years	
	Design	Lancet (3 grinding facettes)	Backbevel (3 grinding facettes)



Product Characteristics		endomina [®] system	endomina [®] EZFuse system
Needle tip design	Dimensions	<ul style="list-style-type: none"> ▪ ID=1,40 + 0,04/-0,01mm ▪ OD=1,80 ± 0,015mm ▪ Length=17 ± 0,3mm ▪ Reduced portion=5 ± 0,2mm ▪ OD Reduced portion=1,60 ± 0,02mm ▪ Main needle grinding angle=15°±1° 	
Device length		1375mm	1295mm
Device length inserted in the platform and patient body		1056 mm	1056 mm
Anchors and suture		Anchors are linked by two braided suture and a knot.	
Dimensions	▪ Suture	2 wires of 0.15 mm in parallel	
	▪ Anchors	1 anchor of 10 mm x 1.1mm OD 1 anchor of 10 mm x 1.1mm OD	1 anchor of 10 mm x 1.2mm OD 1 anchor of 10 mm x 1.1mm OD
Raw materials	<ul style="list-style-type: none"> ▪ Suture ▪ Anchors 	<ul style="list-style-type: none"> ▪ Non-absorbable braided polyester ▪ PEEK (Optima LT2) 	



Non-clinical Performance Data: Appropriate product testing was performed on endomina® EZFuse system to evaluate conformance with standard requirements and substantial equivalence to the predicate device. Verification and validation for the proposed system was conducted in accordance with protocols.

Performance testing:

Bench tests were performed to demonstrate the substantial equivalence of the needle welding, needle heel, needle piercing, tightening fuse break forces, implant strength/breaking force, the handle actuation force during piercing, the functionality (implant release), the performance of the device and the tissue injury of the device.

Sterility:

Sterility claims (SAL 10^{-6}) were confirmed by executing a sterilization validation in accordance with EN ISO 11135:2014 /A1:2019.

Packaging and Shelf-life:

Packaging integrity was confirmed by repeating testing in accordance with ASTM F1929-23 and ASTM F1886-16. Shelf-life claims were confirmed by functional testing on aged products.

Biocompatibility: Biocompatibility testing and toxicological assessments were performed on the predicate and are applicable for all endomina® EZFuse system components in accordance with their risk category requirements, as defined in ISO 10993-1: 2018. Testing included cytotoxicity in accordance with ISO 10993-5: 2009, sensitization in accordance with ISO 10993-10: 2021, irritation in accordance with ISO 10993-10: 2021, acute systemic toxicity in accordance with ISO 10993-11: 2017, material mediated pyrogenicity in accordance with USP <151> and implantation in accordance with ISO 10993-6: 2016.

Clinical Performance Data: Clinical testing was not required to demonstrate substantial equivalence

Basis of Substantial Equivalence: The results of all studies confirmed substantial equivalence between the subject and predicate devices and that no new issues of safety nor efficacy were raised. Based on a comparison of indications for use and technological characteristics, the proposed system has demonstrated substantial equivalence to its predicate.