December 7, 2021

Endo Tools Therapeutics S.A.
Marine Rouyer
International Regulatory Affairs Director
Rue Auguste Piccard 48
Gosselies, 6041
BELGIUM

Re: K211309
Trade/Device Name: endomina system
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCW
Dated: October 25, 2021
Received: October 27, 2021

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Je Hi An, PhD
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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K211309

Device Name

endomina® system

Indications for Use *(Describe)*

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.

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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Submitter Name & Address	Endo Tools Therapeutics S.A. Rue Auguste Piccard 48 6041 Gosselies Belgium
Contact Person	Marine ROUYER International Regulatory Affairs Director regulatory@endotools.be Phone: +32 71 91 94 09
Date:	10 November 2021
Name of Device:	endomina® system
Common or Usual Name:	Endoscopic Tissue Approximation Device
Classification Name:	Endoscope and Accessories
Regulatory Class:	Class II (21 CFR 876.1500)
Product Code:	OCW
Predicate Device:	K171886 – OverStitch™ Endoscopic Suturing System (Apollo Endosurgery)
Device Description:	The endomina® 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 (TAPES). The endomina® system is sterile packaged and designed for single use and is manufactured from various thermoplastic, silicone, stainless steel materials, biocompatible 3D printing materials and other medical grade materials. <u>endomina® platform:</u> The endomina® platform can be assembled on a regular flexible endoscope inside the stomach. It includes a bendable therapeutic channel meant for the endoscopic tool TAPES. 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. <u>TAPES:</u> TAPES is an instrument intended to be used with the endomina® platform and a flexible endoscope for tissue approximation in the gastrointestinal tract. TAPES is inserted in the bendable arm of endomina®'s platform. TAPES 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® 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.

Technological Characteristics:

Product Characteristics		OverStitch™ Endoscopic Suturing System (needle driver, anchor exchange and suture assembly (only its anchor which serves also as a needle))	endomina® system (endomina® platform and TAPES non-implantable parts)
510(k) Clearance		K171886	K211309
Single Use		Yes	
Sterilization		Terminally sterilized to SAL 10^{-6} using a validated EO method	
Shelf-Life Claim		3 years	2 years
Dimensions:	▪ Device length	▪ 130 cm	▪ 108 cm
	▪ Length of device extending from the tip of the endoscope	▪ 17.5 mm	▪ 35 – 43 mm depending on the scope position inside the device
	▪ Distance from the endoscope to the needle	▪ 13.1 mm	▪ 27.5 – 34.5 mm depending on the scope position inside the device
	▪ Diameter at the distal end closed	▪ 16.3 mm	▪ 16.3 mm
	▪ Diameter at the distal end open	▪ 23.3 mm	▪ 14.4 mm + diameter of the endoscope
Compatible Scopes		Dual channel endoscopes Olympus GIF-2TH180 and GIF-2T160	Single channel endoscopes that are 8.5 - 11.0 mm in diameter and no restriction in working length

Product Characteristics	OverStitch™ Endoscopic Suturing System (needle driver, anchor exchange and suture assembly (only its anchor which serves also as a needle))	endomina® system (endomina® platform and TAPES non-implantable parts)
Raw materials	▪ ABS ▪ Stainless Steel	▪ ABS ▪ Stainless Steel ▪ Pellethane ▪ Pebax ▪ VisiJet® Crystal or MED610 ▪ FEP ▪ HDPE ▪ PTFE (coating) ▪ Nitinol ▪ PEEK
Endcap + Scope Position	Capped onto the distal scope face prior to insertion. The handle can be attached to the scope.	Assembly of device with scope is done inside the stomach. The handle is not attached to the scope.
Endcap + Scope Attachment	Interference fit	4 wires (Clamping mechanism)
Angle of the needle when piercing	90° (arc)	90° (perpendicular to axis of vision)
Needle - **Diameter** - **Raw materials**	▪ 1.0 mm ▪ Stainless Steel 316L ▪ Cobalt Chromium MP35	▪ 1.8 mm ▪ Stainless Steel 316L

Product Characteristics		OverStitch™ Endoscopic Suturing System (cinch implantable part and suture assembly)	endomina® system (TAPES implantable parts)
510(k) Clearance		K171886	K211309
Single Use		Yes	Yes
Sterilization		Terminally sterilized to SAL 10^{-6} using a validated EO method	
Number of anchors		2 different anchors: - one being the needle itself - one called cinch	2 similar anchors
Anchors and suture		Anchors are linked by monofilament suture.	Anchors are linked by two, braided sutures and a knot.
Dimensions:	▪ Anchor length	▪ 6.6 mm (needle) – 8.0 mm (cinch)	▪ 10 mm
	▪ Anchor diameter	▪ 1.0 mm (needle) – 2.4 mm (cinch)	▪ 1.1 mm
	▪ Suture length	▪ 185 mm	▪ 80-100 mm
	▪ Suture diameter	▪ 1 wire of 0.3 mm*	▪ 2 wires of 0.15 mm in parallel
Raw materials	▪ Suture	▪ Non-absorbable monofilament Polypropylene (synthetic linear polyolefin) or long-term absorbable monofilament polydioxanone	▪ Non-absorbable braided polyester
	▪ Anchors	▪ VESTAKEEP PEEK ▪ Cobalt Chromium MP35	▪ PEEK (Optima LT2)

Non-clinical Performance Data:

Appropriate product testing was performed on endomina® 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 testing included suture delivery accuracy, needle attachment, pull-off force to remove the distal tip from the endoscope, the size of approximated tissue fold, the force needed to approximate the tissue, the ease of insertion into a patient gastrointestinal tract, the suture strength, the force needed to separate anchors and suture and the needle piercing force.

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 F1929-15 and ASTM F1886-16.
Shelf-life claims were confirmed by functional testing on aged products.

Biocompatibility:

Biocompatibility testing and toxicological assessments were performed on all endomina® system components in accordance with their risk category requirements, as defined in ISO 10993-1: 2018. Testing included chemical characterization in accordance with ISO 10993-18: 2020, cytotoxicity in accordance with ISO 10993-5: 2009, sensitization in accordance with ISO 10993-10: 2010, irritation in accordance with ISO 10993-10: 2010, 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.

Animal Testing:

Animal testing was performed to demonstrate the substantial equivalence of endomina® system with its predicate in regard to ease of use, efficacy and safety during an endoscopic tissue approximation procedure for suturing in a minipigs' stomach.

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.