January 3, 2020

Era Endoscopy s.r.l.
Alberto Arena, Eng
Via Boccioni, 1
56037 Peccioli,
ITALY

Re: K190669
Trade/Device Name: Endotics
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: November 25, 2019
Received: December 2, 2019

Dear Alberto Arena:

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,

Shanil P. Haugen, PhD
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190669

Device Name
Endotics

Indications for Use *(Describe)*

The Endotics System is intended to provide 360° visualization and diagnostic/therapeutic access to the adult lower gastrointestinal tract (including but not limited to, the anus, rectum, sigmoid colon, transverse colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery.

The Endotics Probe (colonoscope component of the Endotics Colonoscope System) is a single use disposable device. The Endotics Probe cannot be reprocessed.

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.

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Section 5 510(k) Summary

I. SUBMITTER

Applicant Information: Era Endoscopy s.r.l.
Via Boccioni, 1 56037
Peccioli (Pi) - Italy

Contact: ing. Alberto Arena (Quality and Regulatory Manager)
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Date Prepared: 1st February 2019

II. DEVICE

Device Trade Name	ENDOTICS
Common Name	Colonoscope And Accessories
Device Class	II
Classification Name	Endoscope and accessories
Regulation	21 CFR 876.1500
Product Code	FDF

III. PREDICATE DEVICE

Legally Marketed Predicate Device (s)

510(k) Number	Product Code	Regulation Number	Trade Name	Applicant
K141286	FDF	21 CFR § 876.1500	Aer-o-scope Colonoscope System	GI View, Ltd.
K121582	FDF	21 CFR § 876.1500	Invendo C25 Colonoscopy System	Invendo Medical GmbH
K001241	FDF	21 CFR § 876.1500	OLYMPUS CF-Q160	Olympus Medical Systems Corporation

IV. Device Description

Endotics is an endoscopic system to be used for the examination of the final section of the intestine, the ends of which are marked by the anal sphincter and by the ileocecal valve, known as the colon-rectum.

The system comprises two parts, which can be sold separately, namely: the“disposable probe”, and the “workstation”, equipped with a command console.

Thanks to its flexibility, the disposable probe can easily adapt its shape to that of the colon. The motion, based on the “caterpillar” principle, is ensured by an anchoring system, placed by the ends of a flexible body.

The colonoscope includes on its distal segment a viewing system, featuring a CMOS digital camera and a LED light source.

The probe is further equipped with a steering system, which enhances the efficiency in terms of both motion and vision (maximum flexion angle: 180° in every direction).

The endoscope is activated pneumatically.

This device allows the use of specific surgical tools through a working channel.

The exit of the working channel is centred compared to the head of the robot and it is located near the camera, which is therefore slightly decentred. When the tool exits the probe, it is immediately detected and the operator can then visually pilot it over the zone to be treated.

The anchoring system performs a double action. By extracting the air from inside the intestine it enables the intestine linings to approach the robot precisely at the point in which they will then be mechanically anchored. This system produces a steady hold on the intestine lining but prevents any damage or trauma from occurring.

Endotics Workstation is composed of an electro-pneumatic system, controlled by a Panel PC which displays the different progress phases of the device and the images delivered by the internal camera, and of a command console for controlling the probe’s movements.

Only the Endotics disposable probe can be connected to this workstation. The probe is linked to the workstation by means of an electro-pneumatic connector. The connector is placed on a twistable arm which is connected to the machine’s main block. This arm is fitted on the inside with pneumatic tubes and electric cables which connect the probe to the workstation’s electro-pneumatic system and which connect the camera (placed by the probe’s head) to a video system. The arm is also equipped with an electronic board which acts as an opto-insulator between the camera and the electric features of the workstation. The electro-pneumatic distributor is controlled by a computerised system, on which specifically designed command software has been installed.

The monitor also displays the probe’s status, indicating its current motion phase e the captured pictures. The associated accessories include:

- Stiffening accessory
- Waterjet accessory

V. Indication for Use

The Endotics System is intended to provide 360° visualization and diagnostic/therapeutic access to the adult lower gastrointestinal tract (including but not limited to, the anus, rectum, sigmoid colon, transverse colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery.

The Endotics Probe (colonoscope component of the Endotics Colonoscope System) is a single use disposable device. The Endotics Probe cannot be reprocessed.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Colonoscopy is the technological principle for both the Endotics and predicate devices. It is based on the use of endoscopic instrumentation for the examination of the final section of the intestine, the ends of which are marked by the anal sphincter and by the ileocecal valve, known as the colon-rectum.

The Endotics and predicate devices (K141286 and K121582) are based on the following same technological elements:

- A controlling workstation
- A single use disposable colonoscope

Like the predicate Aer-o-scope Colonoscope System and Invendo, the ENDOTICS Disposable Probe is not directly manually manipulated by the operator and moves through the colon under the direction and control of the operator using a joystick.

The only difference between Endotics and the predicates consists in propulsion mechanism inside the intestine: Endotics probe is not a pushed device, while the predicates result in externally pushed devices.

In the follow table are reported a side-by-side comparison of technological characteristics of Endotics device and the predicate devices

	Endotics K190669	**Aer-o-scope K141286**	**Invendo C25 K121582**	**Olympus CF-Q160 K001241**
Viewing direction	Forward	OMNY	Forward	Forward
Field of view	140°	Front 90° Angular 360°	114°	Forward 140°
Depth of Field	3-100 mm	Omni- 11-50 mm Front- 10 to 60 mm	-	3–100 mm

	Endotics K190669	**Aer-o-scope K141286**	**Invendo C25 K121582**	**Olympus CF-Q160 K001241**
Chip	CMOS 1M pixels	CMOS 1.3 M pixels	CMOS 0.25M Pixels	CCD color
Illumination	LEDs	LEDs	LEDs	Light guide
Max. diameter insertion point	17.5 mm	13 mm	18 mm	12.8 mm
Multilumen max diameter	7.5 mm	7.5 mm	18 mm	12.8 mm
Working length	2030 mm	2000 mm	2100 mm	1680 mm
Total length	2390 mm	2300 mm	3600 mm	-
Bending capacity	180° in all directions	160° in all directions	180° in all directions	180° Up-down 160° right-left
Diameter working channel	3 mm	-	3.1 mm	3.7 mm
N. of working channels	1	-	1	1
N. of other channels (suction/insufflation Fluids)	1 air/water 2 air	1	1	1 air/water 1water
Power supply base unit	100-240 V 50/60Hz	100-240 V 50/60Hz	100-240 V 50/60Hz	100-240 V 50/60Hz
Max internal pressure base unit	450 KPa	450 KPa	600 KPa	-
Max internal vacuum base unit	-75Kpa	-	-75KPa	-
Workstation weight	37 Kg w/Panel PC	167 Kg	-	-
Workstation dimensions	280 (H) x 650 (W) x 580 (D) mm	1200 (H) x 400 (W) x 600 (D) mm	-	-
Main materials in contact with patient	Silicone, ABS and PVC	Polyurethane, PEBAX and hydrophilic coating	Silicone, polycarbonate and lubricant	-
Type of sterilization	Ethylene Oxide	-	Ethylene Oxide	-
Disposable	YES	YES	YES	NO
Re-processable	NO	No	No	YES

Moreover, the results of the bench tests and clinical tests show that differences in propulsion systems provide equivalent levels of safety and efficacy compared to the predicate devices and that clinical

performance of Endotics compared to conventional colonoscopy systems (see predicate K001241), have the similar characteristics.

The product specification, functionality and indication for use of the ENDOTICS are the same or very similar to the legally marketed, claimed predicate devices for the purpose of this 510(k) submission.

VII. Performance Data

The ENDOTICS has been tested and is in compliance with:

Biocompatibility (according to ISO 10993)

The battery of testing included the following tests:

- Cytotoxicity – Test Report N°2249-1/13 (Attach 13_B Cytotoxicity Test)
- Sensitization – Test Report N°2249-4/13 and N°2249-3/13 (Attach 13_C Sensitization test Apolar and Attach 13_D Sensitization test Polar)
- Irritation/Intracutaneous - Test Report N°2249-2/13 (Attach 13_E Irritation Test)

The disposable probe is considered tissue contacting for a duration of less than 24 hours.

Electrical Safety, Electromagnetic Compatibility EMC (according to EN 60601-1 and EN 60601-1-2)

The battery of testing included the following tests:

- Electrical Safety Test: Test Report R-EL-27-0414-01A (see attachment 15_A)
- Electromagnetic Compatibility: Test Report R-EM-227-0119-01A (see attachment 15_B)

Sterilization Process Validation (According to ISO 11135)

The battery of testing included the following tests:

- Validation Protocol of Sterilization Process (see Attachment 12_A.)
- Validation Report of Sterilization Process (see Attachment 12_B)
- Sterilization Process Validation - ERA Endoscopy and Steril Verona Documentation - Annex 1 (see Attachment 12_C)
- Sterilization Process Validation - Result of Physical Performance - Annex 2 (see Attachment 12_D)
- Sterilization Process Validation – Result of Microbiological Performance - Annex 3 (see Attachment 12_E)

Shelf life (According to ISO 11607-1)

- Medical Devices Shelf-Life (3 years) Final Report (see Attach 12_F Shelf life 3 years validation)

ETSI EN 300-019-2.2 V2.2.1 Enviromental condition and enviromental test for telecomunications equipment; Part 2-2 Specification of enviromental tests; Transportation

- Test Report R-EL-227- 1014 – 02A (Attach 12_G Enviromental Conditions and trasportation test for Workstation)

Software Validation (According to ISO 62304)

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

The documentation of Software Validation can be found in the annexes of Section 14

Usability (According to IEC 62366-1:2015)

The usability of the product was conducted in accordance with IEC 62366-1:2015 and concerns various aspects of the device use.

The documentation can be found in the annexes of Section 16:

- Usability File (see Attachment 16_A)

Mechanical Testing

Bench Test of the Endotics were performed to support the efficacy/safety of the device and substantial equivalence.

Tests carried out have covered the following areas (see Attachment 16_B Bench Testing):

- Mechanical resistance test
- Fatigue strength test
- Breaking Pressure Test
- Tensile Strength Test
- Mechanical Characterization Test
- Simulated use testing

ANIMAL STUDIES

Era Endoscopy during the development of the Endotics System performed a clinical study on animals (Attach 17_A Animal test). The study was designed to provide objective parametric data that allow excluding that the device is imposing relevant trauma with acute or delayed response of the colon tissue.

The study was carried out in the domestic pig model (n=3), female pigs, the post-operative follow-up survival period was 1 week.

The clamping mechanism does not create significant lesions in the bowel wall, such as mucosal lacerations. No bleeding was found as a result of the interaction of the clamping mechanism with the colonic wall. Also in case of prolonged clamping of 5 minutes duration no relevant lesions were seen. The marks on the colonic wall inherent to the procedure proved to be temporary and left no visible remains after a follow-up period of 7 days.

In these regards the clamping system of the device can be considered safe in the animal model. Bowel wall thickness in the adult pig correlates well with the human, therefore we do not anticipate the device clamping mechanism should be harmful for the human colon.

CLINICAL STUDIES

Era Endoscopy, during the Endotics project development, carried out thr following clinical investigations to demonstrate the safety and efficacy of the device.

- Functional evaluation of the Endotics System, a new disposable self-propelled robotic colonoscope: in vitro (see Attachment 18_A).
- Endotics system vs colonoscopy for the detection of polyps (see Attachment 18_B).
- Functional assessment in terms of safety and efficacy of the Endotics system in endoscopic colorectal studies (Attachment 18_C).

The results of this latest study are summarized in the table below:

Title	Functional assessment in terms of safety and efficacy of the Endotics® system in endoscopic colorectal studies
Methodology	Single center, controlled and randomized NO PROFIT study
Study Description	A controlled and randomized NO PROFIT study for the functional evaluation in terms of safety, effectiveness and efficacy of the Endotics® system, a single-use semi-automatic robotic colonoscope, in the identification of colorectal diseases.
Number of patients	Planned: 20; Analysed: 20
Objectives	To evaluate the diagnostic accuracy (efficacy), safety and tolerability for the patient of the Endotics system in comparison with the traditional Colonoscopy
Study Population	20 (twenty) patients, of both sexes, aged between 18 and 65, meeting the inclusion / exclusion criteria, have been recruited, consecutively selected among those in whom routine colonoscopy was indicated.
Criteria for inclusion	Patients aged between 18 and 65 in which a colonoscopy examination was indicated.
Study period	5 months from May to September 2018
Participant Duration	3 days for bowel preparation and 2 hours for both procedures (ENDOTICS and CT).
Statistical methods	The statistical analysis has been conducted according to the principles of the PP/AT analysis (per protocol / as treated). All participants with a recorded exam have been randomized.
Primary Endpoints	**Efficacy**

	Statistical comparison between the PDR/ADR of the TC and that of the ENDOTICS. ENDOTICS have to result not inferior if compared to TC with pvalue< 0.05. Moreover, ADR (ENDOTICS) should be greater or equal than 25% (according to ASGE guidelines). **Safety** Statistical comparison between EA/SEA occurring with the traditional colonoscopy (TC) compared to those occurred with the ENDOTICS. ENDOTICS have to be not inferior to TC with P<0.05.
Secondary Endpoints	Cecal intubation rate: Statistical comparison between CIR (ENDOTICS) and CIR (TC). CIR (ENDOTICS) has to be not inferior to CIR (TC) with pvalue< 0.05. Moreover, CIR (ENDOTICS) should be greater or equal than 90%. Tolerability: Statistical comparison of parameters related to pain and discomfort between ENDOTICS and TC. ENDOTICS has to be superior compared to TC with pvalue< 0.05. Cecal intubation time (CIT) and procedure time (PT): Statistical comparison between CIT/PT of the CT and that of ENDOTICS. CIT/PT (ENDOTICS) must not be inferior compared to CT with p-value<0.05.
Summary Results	**Efficacy** Based on the results of this study, statistically Endotics colonoscopy is at least not less effective and efficient than traditional colonoscopy (see predicate device K001241). Previous studies had already demonstrated the not inferior diagnostic capacity of Endotics if compared to TC, and these data are confirmed by this study. **Safety** No adverse events, minor or serious, or deaths were recorded in this study, so it makes no sense to calculate the statistical parameters that were set (mean, standard deviation and confidence interval). No patient requested sedation either during robotic or traditional procedures. Oxygen saturation was monitored for each patient and there were no cases of vagal crisis. No adverse events occurred during polyp's removal, such as perforation with both types of instruments used in the study. Therefore, it can be concluded that Endotics robotic colonoscopy is no less safe than traditional colonoscopy (see predicate device K001241).

Endotics robotic endoscopic system proved to be effective (ADR compatible with ASGE and CIR guidelines as of 100%), safe (no adverse events, minor or serious, were recorded during the procedure or within the following 30 days) and very well tolerated by patients (on a scale of 0 to 10, it recorded an average discomfort for the entire procedure of 1.45 and an average pain of 1.3). Also compared with the predicate colonoscopy system, Endotics proved to be not inferior and more tolerated by the patient (annoyance ES 1.45 versus 6.5 for TC and pain ES 1.3 versus 7.4 for TC).

VIII. Conclusions

Era Endoscopy s.r.l. has determined, by using comparisons and tests, that Endotics is substantially equivalent to the listed predicate devices in terms of intended use, typical clinical use, operational characteristics, and fundamental technological characteristics.