February 14, 2022

EvoEndo Inc
% Isabella Schmitt
Regulatory Affairs Consultant
Proxima Clinical Research
2450 Holcombe Boulevard
Houston, TX 77021

Re: K213606
Trade/Device Name: EvoEndo Single-Use Endoscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS, FET
Dated: November 12, 2021
Received: November 15, 2021

Dear Isabella Schmitt:

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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213606

Device Name
EvoEndo Single-Use Endoscopy System

Indications for Use *(Describe)*
The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of five years. The gastroscope is a sterile single-use device and can be inserted orally or transnasally.

The EvoEndo Controller is intended for use with an EvoEndo Endoscope for endoscopic diagnosis, treatment, and video observation.

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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3 510(k) Summary

510(k) Owner:

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Date Summary Prepared: 12 November 2021

Trade Name: EvoEndo Single-Use Endoscopy System

Common Name: Gastroscope and accessories, flexible / rigid
Endoscopic video imaging system / component, Gastroenterology-Urology

Classification: Class II

Classification Number: 21 CFR 876.1500

Product Code(s): FDS, FET

Classification Advisory Committee: Gastroenterology / Urology

Predicate Device(s): FUJINON MODEL EG-530N TRANS NASAL INSERTION (K063316)

Boston Scientific EXALT Controller (K193202)

Device Description:

The EvoEndo Endoscopy System is comprised of two regulated components:

- EvoEndo Model LE Single-Use Gastroscope (hereafter referred to as the EvoEndo Endoscope)
- EvoEndo Controller (hereafter referred to as the Controller)

The EvoEndo Endoscope is a sterile, single use gastroscope intended to perform oral or transnasal diagnostic endoscopy in adult and pediatric patients. The EvoEndo Endoscope is ethylene oxide (EO) sterilized and is comprised of:

- Handle
- Umbilical Bundle that includes air, water, and suction lines, as well as the video connector
- Endoscope shaft with HD Camera

The Controller of the EvoEndo Endoscopy System translates the images or video captured by the camera at the distal end of the EvoEndo Endoscope to a monitor via an HDMI cable.

Intended Use / Indications for Use:

The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of five years. The gastroscope is a sterile single-use device and can be inserted orally or transnasally.

The EvoEndo Controller is intended for use with an EvoEndo Endoscope for endoscopic diagnosis, treatment, and video observation.

Technological Characteristics:

The EvoEndo Endoscope allows for oral or transnasal insertion and visualization of the esophagus, stomach, and duodenal bulb in both pediatric and adult patients due to its small outer diameter, working channel compatible with standard accessories, and over 1 m working length. The proximal handle on the EvoEndo Endoscope allows physicians to control the distal tip of the EvoEndo Endoscope with 4-way steering as well as buttons for AWS activation and image and video capture and adjustment. The Controller is intended for video and image processing and translates the

images or video captured by the HD camera at the distal end of the EvoEndo Endoscope via an HDMI cable to a Medical-Grade Monitor (not included with system).

Biocompatibility Testing:

Cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity testing was performed per ISO 10993-1 and the FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'" There were no cytotoxicity, sensitization, irritation, acute systemic toxicity, or material-mediated pyrogenicity concerns associated with the EvoEndo Endoscopy System.

Sterilization Validation:

The EvoEndo Endoscope is packaged individually, provided sterile, labeled for single use only, and sterilized using 100% ethylene oxide (EO) gas in a fixed chamber. Validation performed for the sterilization technique met all acceptance criteria. Functional testing confirmed that sterilization did not impact product safety or effectiveness.

Electrical Safety and EMC Testing:

The Electrical Safety (ES) and Electromagnetic Compatibility (EMC) testing conformed to IEC 60601-1:2005/(R)2012 and A1:2012, IEC 60601-1-2:2014, and IEC 60601-2-18:2009. All acceptance criteria were met.

Software Testing:

The firmware used in the EvoEndo Controller has been determined to be a moderate level of concern. The software in the controller consisting of 6 embedded firmware items is considered off-the-shelf software and, as such, is documented in accordance with the FDA Guidance "Off-The-Shelf Software Use in Medical Devices" (Sep 27, 2019).

Bench Performance Testing:

Visual, dimensional, functional, and transit simulation verification testing was performed on final sterilized EvoEndo Endoscopes. The testing sample size was selected to achieve the % confidence / % reliability ratio predetermined for each specification being tested. In functional testing, devices were verified for camera and video control unit functioning; tip deflection; air, water, and suction flow rates; functionality with accessory device; functionality after 360° bend shaft orientation; functionality with simulated repeated use; and post simulated use functionality. The maximum bending angle of the device in each direction is shown in the table below. The deflection achieved with the EvoEndo Endoscope is consistent with that of the identified predicate device in all directions, indicating substantial equivalence.

Table 1: Deflection of EvoEndo Endoscope

Deflection Direction	Maximum Bending Angle
Up	210°
Down	90°
Left	100°
Right	100°

In transit simulation testing, test units underwent environmental conditioning, distribution simulation, and packaging testing to confirm the integrity of the sterile barrier and functionality of the device under expected transportation conditions. The EvoEndo Endoscopy System met acceptance criteria set for all verification testing procedures.

Optical performance testing was performed on the EvoEndo Endoscope and compared to the predicate device. The testing evaluated the resolution, depth of field, geometric distortion, image intensity uniformity, and color performance of the endoscope. The test results suggest equivalent performance across all metrics assessed, demonstrating substantial equivalence between the EvoEndo Endoscope and the predicate device.

Photobiological safety testing was performed per FDA recognized consensus standard IEC/TR 62471 First Edition 2006-07: Photobiological safety of lamps and lamp systems. Based on the measured output of the EvoEndo's light source, it was deemed to be below the limits of the exempt risk group.

Human Factors / Usability Engineering Testing:

EvoEndo conducted a two-stage usability study of representative intended users. The study assessed the overall usability of the EvoEndo Endoscopy System and the ability for users to perform critical tasks. Participants were asked to perform the entire workflow of the device across a benchtop model session and a representative animal model session with prior training provided. Tests were performed in a simulated clinic-office setting. Throughout the procedure, there were no significant device or user malfunctions or errors that would result in patient harm during an actual procedure.

Animal Testing:

Animal testing was not required for this device.

Clinical Testing:

Clinical testing was not required for this device.

Conclusion:

In conclusion, the EvoEndo Single-Use Endoscopy System is demonstrated to be as safe and effective and perform as well as the identified predicate devices. The EvoEndo Endoscope and Controller have the same intended use, indication, technological characteristics, and principles of operation as the respective predicates. Any differences between the EvoEndo Endoscopy System and the predicate devices do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when use as labelled. Verification and usability testing demonstrate that the device performs as intended. Thus, the EvoEndo Endoscopy System is substantially equivalent to the identified predicate devices.