April 14, 2023

Covidien LLC
Liron Yaakov
Sr. Manager Regulatory Affairs
3062 Bunker Hill Lane
Santa Clara, CA 95054

Re: K223705
Trade/Device Name: EndoflipTM 300
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: FFX
Dated: March 10, 2023
Received: March 14, 2023

Dear Liron Yaakov:

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 -S

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)*
K223705

Device Name
Endoflip™ 300 System

Indications for Use *(Describe)*
The Endoflip™ 300 System is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters in adults and to measure pressure and dimensions in the esophagus, in patients from 5 years of age. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

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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510(k) Summary

I. SUBMITTER

Covidien llc (Medtronic)
3062 Bunker Hill Lane
Santa Clara, CA 95054

Contact Person: Liron Bar Yaakov
Sr. Manager Regulatory Affairs

Telephone: 720-422-9135
E-mail: liron.baryaakov@medtronic.com

Date Prepared: March 6, 2023

II. DEVICE

Name of Device:	Endoflip™ 300 System
Common or Usual Name:	System, Gastrointestinal Motility (Electrical)
Classification Name:	Gastrointestinal motility monitoring system (21 CFR 876.1725)
Regulatory Class:	II
Product Code:	FFX

III. PREDICATE DEVICE

Predicate Name:	Endoflip™ System
Predicate 510(k) number:	K183072

This submission also used a reference device:

Reference Name:	FLIP Topography Module
Reference 510(k) number:	K170833

IV. DEVICE DESCRIPTION

The Endoflip™ 300 System is the next generation of the predicate Endoflip™ System consisting of design changes to the device hardware and software components. The design changes improve device usability when compared to the predicate. Changes were made to the platform components only; no design changes were made to the system catheters (Endoflip™ or Esoflip™) except for labeling changes (not related to indications for use).

The following table provides a summary of the Endoflip™ 300 System platform components:

Table 1. Summary of Endoflip™ 300 System Platform Components

REF	Component Name	Device Use
EF-301	Endoflip™ 300 Pump System *	Capital equipment, reusable
EF-302	Endoflip™ 300 Display System	Capital equipment, reusable, supplied with Endoflip™ 300 System software pre-installed
EF-303	Endoflip™ 300 Cart	Capital equipment, reusable, contains an isolation transformer
EF-304	Endoflip™ 300 Reader	Standalone software accessory, downloaded to a personal computer
EF-305	Pre-Use Tube	Accessory, reusable

*A refurbished pump system is also available with REF number EF-301-RFB.

A description of each platform component is provided below:

Endoflip™ 300 Pump System

The Endoflip™ 300 Pump System is a hardware device that runs on a PIC32MZ microcontroller. It is responsible for data acquisition from an Endoflip™ or Esoflip™ balloon catheter and controlling a syringe pump drive, which inflates or deflates the balloon with conductive saline solution. The pump system firmware is designed to be controlled by the Endoflip™ 300 Software via an API command set that allows access and control of all peripherals. This allows the Endoflip™ 300 Display System to contain all the application and business logic of the Endoflip™ 300 System. The pump system also contains bootloader firmware that can support firmware upgrades via an Ethernet connection. The Endoflip™ 300 Pump System connects to the Endoflip™ 300 Display System via an Ethernet cable.

Endoflip™ 300 Display System

The Endoflip™ 300 Display System is a hardware device consisting of an off-the-shelf medical grade touchscreen computer. It is provided to the user preinstalled with the Endoflip™ 300 System software in Normal Mode (also referred to as Acquisition Mode), Installer, IT Utility and OS. The display system serves as the primary user interface that allows the user to perform an Endoflip™ procedure, visualize data and create reports. It also provides the option to the user to connect to a clinic or hospital network via Ethernet.

Endoflip™ 300 Cart

The Endoflip™ 300 Cart provides a secure mounting location for the pump and display systems allowing movement of the system within the clinical setting. It includes an isolation transformer at its base and a holder for the Pre-Use Tube. It is also provided to the user pre-wired to connect to an electrical source and with an Ethernet cable to connect the pump and display systems to each other.

Endoflip™ 300 Reader

The Endoflip™ 300 Reader is a standalone software application that allows review of study data on computers other than the Endoflip™ 300 Display System. It is meant to be used by healthcare professionals to evaluate Endoflip™ data post-procedure. The Endoflip™ 300 Reader is installed from a USB device.

Pre-Use Tube

The Pre-Use Tube is a stainless-steel tube that is slid into the pre-use tube holder found on the right-hand side of the cart. It is meant to hold the distal end of an Endoflip™ or Esoflip™ catheter during pre-check.

V. INDICATIONS FOR USE

The Endoflip™ 300 System is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters in adults and to measure pressure and dimensions in the esophagus, in patients from 5 years of age. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

There is no change to the indications for use when compared to the predicate device.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Gastrointestinal motility assessment using impedance planimetry is the technological principle for both the subject and predicate devices. It requires use of a platform that includes a pump, display and cart and balloon catheters that work as functional lumen imaging probes to characterize the geometry of the measurement area. At a high level, the subject and predicate devices (including the reference device) are based on the same technological elements:

- System comprised of a pump, display, cart and accessories, including pre-use tube and balloon catheters
- Compatibility with the same, previously cleared catheters – Endoflip™ and Esoflip™
- Pump is firmware controlled to move the syringe driver to inflate/deflate the balloon with saline
- Real-time geometric image of the measurement area
- Provides estimated balloon diameters along the length of the balloon and historical diameter estimates and other parameters

The following high level technological differences exist between the subject and predicate devices:

- Fully integrated platform with redesigned hardware components
- Guided catheter setup during pre-check
- Key metrics capture
- Additional data analysis capabilities
- Study manager feature – save studies and reports for post-procedural review
- Network connectivity

VII. PERFORMANCE DATA

The following performance data were evaluated and, if applicable, provided in support of the substantial equivalence determination.

Biocompatibility Testing
Biocompatibility testing is not applicable since none of the Endoflip™ 300 System platform components evaluated are patient contacting.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were performed on the Endoflip™ 300 System platform. The system complies with IEC 60601-1 (US Dev. ANSI AAMI ES60601-1) for safety and IEC 60601-1-2 for EMC.

Software Verification and Validation Testing
Software verification and validation testing were performed per IEC 62304, 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 a "moderate" level of concern since prior to mitigation of hazards a failure of the software could result in minor injury or a malfunction of, or a latent design flaw in, the software could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to a minor injury.

Mechanical Testing
Mechanical testing was performed on the Endoflip™ 300 System platform. Testing performed includes:

- Physical attribute verification
- Unpackaged and packaged weight maximums
- Syringe locking mechanism and syringe detection mechanism
- Catheter connector mechanism, pre-use tube and catheter support
- Accessible and replaceable air filtration
- Extended syringe, manual retraction and balloon deflation
- Syringe delivery and extraction rate
- Syringe pressure delivery
- Ingress protection
- Mechanical strength
- Acoustic energy

Reliability Testing
Reliability testing was performed on the Endoflip™ 300 System platform to demonstrate the device meets a 5-year useful life.

Environmental Testing
Environmental testing was performed on the Endoflip™ 300 System platform to verify device operational and storage conditions.

Usability Study
Usability validation was performed per IEC 62366 to assess the design changes to the Endoflip™ 300 System. Design changes were found to be adequately safe and effective for its intended uses, by the intended users, in a simulated intended-use environment.

Animal Studies
Animal studies were not required to demonstrate the safety and performance of the Endoflip™ 300 System.

Clinical Studies
Clinical studies were not required to demonstrate the safety and performance of the Endoflip™ 300 System.

VIII. CONCLUSION
The Endoflip™ 300 System is substantially equivalent to the predicate device. The subject device has the same device classification, intended use, intended use environment, target patient population and principles of operation as the predicate. The subject device design and technological differences do not raise any new questions of safety and effectiveness when compared to the predicate, which is supported by the verification and validations activities performed.