July 21, 2023

Covidien LLC
Viviana Gonzalez
Sr. Regulatory Affairs Specialist
3062 Bunker Hill Lane
Santa Clara, CA 95054

Re: K231861
Trade/Device Name: Endoflip™ 300 System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: FFX
Dated: June 22, 2023
Received: June 23, 2023

Dear Viviana Gonzalez:

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)*
K231861

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 five 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 006 – 510(k) Summary

I. SUBMITTER

Covidien llc (Medtronic)
3062 Bunker Hill Lane
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Contact Person: Viviana I. González
Sr. Regulatory Affairs Specialist

Telephone: 410-940-9773
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Date Prepared: June 19, 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™ 300 System
Predicate 510(k) number: K223705

IV. DEVICE DESCRIPTION

The subject Endoflip™ 300 System is equivalent to the predicate Endoflip™ 300 System (K223705) except for an update to the Endoflip™ 300 System software to remove the analysis episode feature of the predicate device. Other software updates include minor feature enhancements and bug fixes. Changes to device labeling resulting from the software updates and other minor changes for clarification purposes were also addressed.

The Endoflip™ 300 System software is supplied pre-installed in the Endoflip™ 300 Display System. It is also the software used for the Endoflip™ 300 Reader in reader mode only. There is no change to the display system hardware or to how the reader is supplied (USB stick).

No changes were made to any of the other components that comprise the Endoflip™ 300 System when compared to the predicate.

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.

VI. 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 are based on the same technological elements:

- System comprised of a pump, display, cart and accessories, including pre-use tube, reader software and 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
- Fully integrated platform
- Guided catheter setup during pre-check
- Key metrics capture
- Study manager feature – save studies and reports for post-procedural review
- Network connectivity

VII. PERFORMANCE DATA
Only software verification was necessary to establish substantial equivalence with the predicate device.

Software verification testing was performed per IEC 62304, and documentation was provided as recommended by the following FDA guidances: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 2005) and *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* (July 28, 2014). 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.

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 changes do not raise any new questions of safety and effectiveness when compared to the predicate and are supported by verification activities performed.