DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 14, 2016

Given Imaging, Ltd.
Hilla Debby
Director, Clinical & Regulatory
2 Hacarmel St. New Industrial Park POB 258
Yoqneam, 20962
Israel

Re: K153466
Trade/Device Name: PillCam COLON 2 Capsule Endoscopy System
Regulation Number: 21 CFR§ 876.1330
Regulation Name: Colon capsule imaging system
Regulatory Class: II
Product Code: PGD
Dated: November 30, 2015
Received: December 1, 2015

Dear Hilla Debby,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153466

Device Name
PillCam COLON 2 Capsule Endoscopy Sysytem

Indications for Use *(Describe)*
The PillCam COLON 2 capsule endoscopy system is intended to provide visualization of the colon. It may be used for detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible. In addition, it is intended for detection of colon polyps in patients with evidence of gastrointestinal bleeding of lower GI origin. This applies only to patients with major risks for colonoscopy or moderate sedation, but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.

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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Given Imaging Ltd. (GI Solutions, Medtronic) 2 Hacarmel Street New Industrial Park PO Box 258 Yokneam 20692 Israel Tel.: 011-972-4-9097774 Fax: 011-972-73-2501533
Contact Person:	Hila Debby Director, Clinical & Regulatory Email: Hila.Debby@covidien.com
Phone Number:	972 (4) 909-7774
Fax Number:	(972) 73-2501533
Establishment Registration Number:	9710107
Date Prepared:	January 13, 2016
Device Trade Name(s):	PillCam® COLON 2 capsule endoscopy system
Device Common Name:	Colon capsule imaging system
Classification:	Regulation No: 876.1330, Class: II Panel: Gastroenterology/Urology PGD– Colon Capsule Imaging System
Predicate Device(s):	PillCam COLON 2 capsule endoscopy system (DEN 120023)

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General Device Description:

The Given PillCam Endoscopy system is comprised of four main subsystems; (1) the ingestible PillCam capsule, (2) the DR 3 PillCam Recorder, (3) the RAPID software, and (4) the Given Workstation and Accessories.

1. *Ingestible PillCam Capsule*
   The disposable, ingestible PillCam Capsule is designed to acquire video images during the natural propulsion through the GI tract. The capsule transmits the acquired images via a RF communication channel to the PillCam Recorder located outside the body.

2. *DR 3 PillCam Recorder*
   The DR 3 PillCam Recorder is an external receiving/recording unit that receives and stores the acquired images from the capsule. The Sensor Array/belt receives data from the PillCam capsule and transfers the data to the PillCam Recorder.

3. *RAPID Software*
   The RAPID Software is a software application that is utilized to process, analyze, store, and view the acquired images collected from the PillCam Recorder to create a RAPID video of the images. The software also includes a reporting function to create detailed clinical reports, in-service training videos, and patient instruction forms.

4. *Given Workstation and Accessories*
   The Workstation is a modified standard personal computer that is the operational platform for the RAPID software. Other accessories include a flat panel LCD monitor, a high-capacity mass storage device, and a high-capacity USB portable storage device.

Indications for use:

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	moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy. According to the expanded indication above, PilllCam COLON 2 capsule can be used for detection of polyps in a group of patients who may not be good candidates for colonoscopy. Pillcam COLON 2 capsule procedure would help the doctors decide whether or not they want to perform the scoping, when there is a strong clinical suspicion of a large polyp or cancer and the patient is at significant risk with colonoscopy or sedation but can tolerate colonoscopy if necessary.
Technological Characteristics:	The technological characteristics of the system (Ingestible PillCam Capsule, DR 3 PillCam Recorder, RAPID Software, Given Workstation and Accessories) are identical to the predicate device (DEN120023).
Optical Features	Same as the predicate device (DEN 120023)
Bench testing:	Same as the predicate device (DEN 120023)
Clinical testing	No clinical testing was performed or relied on for a determination of substantial equivalence.
Performance Data:	The device meets the special controls for colon capsule imaging systems, as described in 21CFR 876.1330.
Conclusion:	The device that is submitted for an expanded indication is identical to an already cleared device (DEN 120023).