March 8, 2018

Given Imaging Ltd.
Hilla Debby
Regulatory Affairs Director
2 Hacarmet St. New Industrial Park
POB 258
Yoqneam, 20692
Israel

Re: K180171
Trade/Device Name: PillCam Patency System
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: II
Product Code: NEZ, NSI, PGD
Dated: January 15, 2018
Received: January 22, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180171

Device Name
PillCam Patency System

Indications for Use *(Describe)*
The PillCam Patency System is an accessory to the PillCam video capsule and is intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures. The PillCam Patency capsule should only be used within the specified patient age range based on the patient age of the indicated video capsule system.

Therefore, the PillCam Patency System is intended to be used:

- prior to PillCam SB capsule in adults and children from 2 years of age, or
- prior to PillCam UGI, COLON, and Crohn's capsules in adults

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

Submitter Name and Address:	Given Imaging Ltd. (Medtronic) 2 Hacarmel Street New Industrial Park PO Box 258 Yokneam 20692 Israel
Contact Person:	Hilla Debby Regulatory Affairs Director Email: Hilla.Debby@medtronic.com
Phone Number:	972 (4) 9097774
Fax Number:	972 (73) 2501533
Establishment Registration Number:	9710107
Date Prepared:	March 5, 2018

II. DEVICE

Device Trade Name(s):	PillCam Patency System
Device Common Name:	Ingestible telemetric gastrointestinal capsule imaging system
Classification:	Regulation No: 876.1300, Class: II: Ingestible telemetric gastrointestinal capsule imaging system, Product Code NEZ: Ingestible telemetric gastrointestinal capsule imaging system and NSI: Ingestible telemetric gastrointestinal capsule imaging system Regulation No: 876.1330, Class II: Colon capsule endoscopy system, Product Code PGD: Colon capsule endoscopy system. Panel: Gastroenterology/Urology

III. PREDICATE DEVICE(S)

Given AGILE Patency System and Given Platform with PillCam SB Capsules (K090557)

IV. DEVICE DESCRIPTION:

There is no change between the Predicate device (K090557) and PillCam Patency System.

The PillCam Patency System is an accessory to the PillCam capsule endoscopy (CE) System and it is used for verifying the patency of the Gastrointestinal (GI) tract. The PillCam Patency System consists of the following components; The PillCam Patency capsule, the Patency scanner and TesTag (interference tester).

The Patency capsule is an ingestible and dissolvable capsule, similar in size to the PillCam CE. It is comprised of a body that surrounds a small Radio Frequency Identification (RFID) tag. The body is coated with an impermeable membrane, except for two small windows that are plugged by the Timer Plugs. The Timer plugs seal the capsule's body. If the Patency capsule is excreted structurally whole, then this confirms patency of the GI tract of the patient for objects similar in size to the capsule. However, if the capsule is retained in the GI tract, the Timer Plugs erode, allowing the penetration of body fluids into the capsule and the dissolution of the capsule's body. The remaining fragments of the capsule can pass even small orifices.

The Patency scanner may be utilized to detect RF signals from the RFID tag, to verify the PillCam Patency capsule presence in the body.

The only difference between the PillCam Patency System and the predicate device is the proposed labeling modification, to allow the use of the existing Patency capsule with the PillCam capsules that are slightly longer (PillCam COLON, Crohn's and UGI capsules). The intention of the proposed change is to offer physicians a clinical tool to evaluate the suitability of patients for CE, as an alternative to magnetic resonance enterography (MRE) or Computed Tomography (CT) which are already used in practice for this purpose.

V. INDICATIONS FOR USE:

The PillCam Patency System is an accessory to the PillCam video capsule and is intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures. The PillCam

Patency capsule should only be used within the specified patient age range based on the patient age of the indicated video capsule system.

Therefore, the PillCam Patency System is intended to be used:

- prior to PillCam SB capsule in adults and children from 2 years of age, or
- prior to PillCam UGI, COLON, and Crohn's capsules in adults

VI. TECHNOLOGICAL CHARACHTERISTICS:

There is no change in the technological characteristics of PillCam Patency System from the cleared predicate device (K090557).

VII. PERFORMANCE DATA:

The PillCam Patency capsule is designed to start dissolving after 30 hours. Clinical testing provided in K053639 was leveraged in this submission. In this testing, patients with known strictures ingested the Patency capsule and underwent periodic scanning until the capsule was excreted. If patency was established, capsule endoscopy procedure was performed. The results of this testing showed there were no cases of capsule retention.

Clinical Evaluation

Many studies in the literature have shown that the PillCam Patency System has high diagnostic sensitivity and specificity and that the use of a PillCam Patency System reduces risk of PillCam CE retention.

In addition, three clinical investigations demonstrate the use of Patency System prior to ingestion of longer PillCam capsules with no safety concern raised.

Key opinion leaders (KOL) in the Inflammatory Bowel Disease (IBD) community have advised, based on their clinical experience, that it is the diameter, and not the length, which is critical for capsule passage through the GI tract. The length is not expected to represent an impediment to passage of the capsule.

The proposed change in this submission does not raise new performance or safety issues.

VIII. CONCLUSION:

Based on the clinical evaluation presented, the company believes that the PillCam Patency System and the predicate device are substantially equivalent and do not raise new issues of safety or effectiveness.