September 1, 2017

Given Imaging Ltd.
Hilla Debby
Director, Clinical & Regulatory
2 Hacarmel Stret, New Industrial Park, P.O. Box 258
Yokneam, 20692
Israel

Re: K170210
Trade/Device Name: PillCam SBC capsule endoscopy system, PillCam Desktop Software 9.0
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: II
Product Code: NEZ, PGD
Dated: July 24, 2017
Received: July 27, 2017

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 (DICE) 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 (DICE) 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,

Charles Viviano -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
Information Unless a Currently Valid OMB Number.
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

Office of Drug Information
Office of Drug Administration
Department of Health and Human Services

Do not send your completed form to the PHA Staff at the address below.

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

Continue on a separate page if needed.

Prescription use (Part 21 CFR 80.100; Part 21 CFR 80.101; Part 21 CFR 80.102)

Type of use (specify one of both, if applicable)

Use in adults.

• The Pilllcam SB capsule may be used as a tool in the detection of abnormalities of the small bowel. It is intended for use in adults.

• It may be used in the visualization and monitoring of the small bowel of patients with colorectal carcinoma-diagnosed colorectal carcinoma.

• It may be used in the visualization and monitoring of the small bowel in patients with colorectal carcinoma against colorectal carcinoma.

• It may be used in the visualization and monitoring of the small bowel in patients with colorectal carcinoma.

Indications for use (please list)
The Pillcam SB capsule may be used as a tool in the detection of abnormalities of the small bowel. It is intended for use in adults.

- The Pillcam SB capsule may be used as a tool in the detection of abnormalities of the small bowel. It is intended for use in adults.
- The Pillcam SB capsule may be used in the visualization and monitoring of the small bowel of patients with osteoporosis, liver cirrhosis, or the visualization of the colon in patients with Crohn's disease.
- The Pillcam SB capsule may be used in the visualization and monitoring of the small bowel of patients with liver cirrhosis.
- The Pillcam SB capsule is intended for visualization of the small bowel and colonic mucosa with Pillcam SB capsule.
510(k) Summary

I. SUBMITTER
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Establishment Registration Number: 9710107
Date Prepared: September 1, 2017

II. DEVICE
Device Trade Name(s): PillCam SBC capsule endoscopy system, PillCam Desktop Software 9.0

Device Common Name: Ingestible telemetric gastrointestinal capsule imaging system

III. PREDICATE DEVICE(S)

- Given PillCam® SB 3 capsule endoscopy system and Given PillCam® endoscopy system with RAPID® 8.0 (K123864) – Primary Predicate
- PillCam® COLON 2 capsule endoscopy system (K153466) – Additional Predicate

IV. DEVICE DESCRIPTION:

The PillCam SBC capsule endoscopy system is comprised of four main subsystems; (1) the ingestible PillCam SBC capsule, (2) the PillCam Recorder DR3, (3) the PillCam Software (a new version of the formerly branded “RAPID” software), and (4) the Workstation and/or accessories.

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

2. PillCam Recorder DR3
The PillCam Recorder DR3 is an external receiving/recording unit that receives and stores the acquired images from the capsule.

3. PillCam Software
The PillCam Software (previously branded as “RAPID” Software) 9.0 is a software application that is utilized to process, analyze, store, and view the acquired images collected from the PillCam Recorder to create a video of the images. The software also includes a reporting function to create detailed clinical reports, in-service training videos, and patient instruction forms. PillCam Desktop Software 9.0 supports PillCam capsule endoscopy of the gastrointestinal (GI) tract with all PillCam video capsules (SB, COLON, UGI and SBC).

4. Workstation and Accessories
The Workstation is a modified standard personal computer that is the operational platform for the PillCam software. The Sensor array or sensor belt receive data from the PillCam capsule and transfer the data to the PillCam Recorder DR3.
V. INDICATIONS FOR USE:
The PillCam SBC capsule is intended for visualization of the small bowel and colonic mucosa.

- It may be used in the visualization and monitoring of lesions in the small bowel that may indicate Crohn’s disease not detected by upper and lower endoscopy, and for the visualization of inflammation of the colon in patients with colonoscopy-diagnosed Crohn’s disease.
- It may be used in the visualization and monitoring in the small bowel of lesions that may be a source of obscure bleeding (either overt or occult) or that may be potential causes of iron deficiency anemia (IDA) not detected by initial upper and lower endoscopy.
- The PillCam SBC capsule may be used as a tool in the detection of abnormalities of the small bowel. It is intended for use in adults.

PillCam Desktop Software 9.0 indications for use:

With PillCam SB 2/ SB 3 Capsule

The PillCam SB 2/ SB 3 capsule is intended for visualization of the small bowel mucosa.

- It may be used in the visualization and monitoring of lesions that may indicate Crohn’s disease not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy.

The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas.

The PillCam SB 2/ SB 3 capsule may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults and children from two years of age.

With PillCam UGI Capsule

The PillCam UGI capsule endoscopy system is intended for visualization of the upper gastrointestinal tract (esophagus, stomach, duodenum). It may be used for visualization of
blood in the upper gastrointestinal tract (esophagus, stomach, duodenum) in patients who are hemodynamically stable and at least 18 years of age.

**With PillCam COLON 2 Capsule**

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.

**With PillCam SBC Capsule**

The PillCam SBC capsule is intended for visualization of the small bowel and colonic mucosa.

- It may be used in the visualization and monitoring of lesions in the small bowel that may indicate Crohn’s disease not detected by upper and lower endoscopy, and for the visualization of inflammation of the colon in patients with colonoscopy-diagnosed Crohn’s disease.
- It may be used in the visualization and monitoring in the small bowel of lesions that may be a source of obscure bleeding (either overt or occult) or that may be potential causes of iron deficiency anemia (IDA) not detected by initial upper and lower endoscopy.
- The PillCam SBC capsule may be used as a tool in the detection of abnormalities of the small bowel. It is intended for use in adults.

**VI. TECHNOLOGICAL CHARACTERISTICS:**

The technological characteristics are similar to the predicate device, PillCam COLON 2 capsule endoscopy system. The only difference between PillCam SBC capsule and PillCam COLON 2 capsule is the programming of the Adaptive Frame Rate (AFR).

Regarding PillCam Desktop Software 9.0, the main difference as compared to previous software versions is the support of PillCam SBC capsule endoscopy procedures, some minor
improvements to existing tools and an improved user interface and complimentary tools. These tools include: improved viewing mode (demonstrated by collage view capability), Dynamic Player Control, enhanced atlas that provides reference images, a tool to aid in ulcer size estimation, GI Map which provides a graphical representation of the small bowel and colon and the progress of the capsule and a tool that displays the 100 most clinically relevant images. The features of PillCam Desktop Software 9.0 create a user-friendly software which may enhance user’s viewing experience. None of the presented changes raise any new safety issues.

VII. PERFORMANCE DATA:

The proposed changes in this submission do not raise new performance or safety issues.

Optical Features
4 white LEDs per optical head are used as the SBC capsule illumination source. The optical Field of view from the entrance pupil is 168° and the Effective Visibility distance is set to 30mm. features are identical as PillCam COLON 2 capsule.

Bench Testing
Since PillCam SBC capsule and the COLON 2 capsule predicate device are identical in terms of external components and technology, the following tests have been verified on PillCam COLON 2 and are applicable for PillCam SBC capsules as well:

- Biting test
- pH resistance test
- Optical resolution
- Optical verification including field of View and depth of focus

Additional bench test that were conducted with PillCam SBC capsule, PillCam Desktop Software 9.0 are:

- Verification of frame rate
• Shelf life and battery evaluation

• Color reproducibility

• Image quality

In addition, PillCam Desktop Software 9.0 was validated and documented per FDA’s software guidance document.

VIII. CONCLUSION:

Based on the technological characteristics of the devices, GI Solutions believes that the PillCam SBC capsule, PillCam Desktop Software 9.0 and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.