June 30, 2023

Given Imaging Ltd. (Medtronic)
Breanna Hessler
Sr. Regulatory Affairs Specialist
2 Hacarmel St. New Industrial Park, PO Box 258
Yoqneam, 20692
ISRAEL

Re: K230991
Trade/Device Name: PillCam SB 3 capsule endoscopy system, PillCam Software 9.0E
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: Class II
Product Code: NEZ
Dated: June 20, 2023
Received: June 21, 2023

Dear Breanna Hessler:

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)*
K230991

Device Name

PillCam SB 3 Capsule Endoscopy System
PillCam Software 9.0E

Indications for Use *(Describe)*

The PillCam 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 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.

Type of Use *(Select one or both, as applicable)*

X 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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1.0 510(k) SUMMARY

Given Imaging Ltd. (d.b.a. Medtronic Inc.)

PillCam SB 3 Capsule Endoscopy System with

PillCam Software 9.0E (including PillCam Cloud Reader Software)

Date Prepared: June 9, 2023

Submitter: Given Imaging Ltd. (d.b.a. Medtronic)
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Contact Person: Breanna Hessler
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Name of Device:

PillCam SB 3 Capsule Endoscopy System with PillCam Software 9.0E (including PillCam Cloud Reader Software)

Common or Usual Name:

Ingestible telemetric gastrointestinal capsule imaging system

Classification:

System, Imaging, Gastrointestinal, Wireless, Capsule

Regulatory Class:

Class II, 21 CFR 876.1300

Product Code:

NEZ

Predicate Device:

PillCam SB 3 Capsule Endoscopy System with PillCam Software 9.0E (K211684)

Subject Device Description:

The subject device, PillCam Cloud Reader SW, is an additional cloud data management option which enables users to review PillCam CE videos stored on the public cloud repository.

The PillCam Cloud Reader SW utilizes Amazon Cloud Services (also referred to as "HCP Cloud" or "AWS") offering a vast standardized, robust, and verified platform that facilities multiple containers while utilizing various cloud services. AWS enables easy and efficient scaling up and down, leveraging the system's efficiency for the PillCam Cloud Reader SW.

The AWS cloud environment is comprised of 2 components: the Cloud Reader Video Storage and HCP Software Application, refer to Section 5.3 for further technological details of each component.

The PillCam Sync Agent is a local software component that is installed in the PillCam Software 9.0E workstation. The PSA continuously sycronizes the local data from the local database (predicate component #4 in the figure below) back and forth to the PillCam Cloud Reader Video Storage component.

Intended Use/Indications for Use:

The PillCam 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 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.

Technological Characteristics:

The proposed PillCam Cloud Reader is an optional reporting subcomponent of the predicate device PillCam SB 3 Capsule Endoscopy System with PillCam Software 9.0E. PillCam Cloud Reader allows physicians to remotely view and report videos that have been generated with PillCam Software 9.0E. PillCam Cloud Reader implements a similar user interface as the existing video viewing and reporting web subcomponent within the PillCam Software 9.0E subsystem, while implementing a different cloud-enabled back end to add scalability and efficiency.

PillCam Cloud Reader is a software application that is utilized to view videos and create reports and does not process and/or analyze acquired images. Input videos are displayed with no processing or alteration. The compilation of the video from the acquired images is still conducted using the predicate device PillCam capsule endoscopy system with PillCam Software 9.0E workstation component.

Non-Clinical Performance Assessment:

The protocols, test methods, and acceptance criteria used for verification of the proposed PillCam Cloud Reader are well established methods. The information summarized in Table 7-1: Design Controls Activities Summary for PillCam Cloud Reader Software, including related risks and risk mitigations, are based on the PillCam Cloud Reader Software risk management plan and summary. These well established methods are in agreement with recommendations in the applicable FDA recognized census standards listed in Section 9.0.

Conclusion:

Medtronic believes that the proposed PillCam capsule endoscopy system with PillCam Software 9.0E (including PillCam Cloud Reader) is substantially equivalent with no impact to safety, efficacy or performance to the device.