August 27, 2021

Given Imaging Ltd. (Medtronic)
% Randy Prebula
Partner
Hogan Lovells US LLP
555 13th Street, NW
Washington, DC 20004

Re: K211684
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 1, 2021
Received: June 1, 2021

Dear Randy Prebula:

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,

for
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)*
K211684

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY

Medtronic's PillCam

SB 3 capsule endoscopy system

PillCam Software 9.0E

Submitter

Given Imaging Ltd. (a Medtronic company)
2 Hacarmel St. New Industrial Park, PO Box 258
Yoqneam, 20692
Israel

Phone: +972-73-2501577

Contact Person: Efrat Shamgar, Sr. Regulatory Affairs Specialist

Date Prepared: June 1, 2021

Name of Device:

PillCam SB 3 Capsule endoscopy system with PillCam Software 9.0E

Common or Usual Name:

Ingestible telemetric gastrointestinal capsule imaging system

Classification Name:

Ingestible telemetric gastrointestinal capsule imaging system

Regulatory Class:

Class II, 21 CFR 876.1300

Product Code:

NEZ

Predicate Devices

Given PillCam SB 3 capsule endoscopy system and Given PillCam® endoscopy system with RAPID 8.0 (K123864) – Primary Predicate

Given Imaging PillCam SBC capsule endoscopy system and PillCam Desktop Software 9.0 (K170210) – Secondary Predicate

Device Description

The PillCam SB 3 Capsule endoscopy system is a device that provides visualization of the small bowel mucosa. The device was previously cleared under 510(k) submission K123864 for the SB 3 Capsule, PillCam DR3 recorder and accessories, and K170210 incorporated the PillCam Software 9.0 to the device. The device is comprised of four main subsystems further described below.

Ingestible PillCam SB 3 Capsule

The disposable, ingestible PillCam SB 3 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 DR3 recorder located outside the body.

PillCam DR3 Recorder

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

PillCam Software

The PillCam Software 9.0E is a software application that is utilized to process, analyze, store, and view the acquired images collected from the PillCam DR3 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 Software 9.0E supports PillCam capsule endoscopy of the gastrointestinal (GI) tract with all PillCam capsules (SB, COLON, UGI and SBC (renamed Crohn's)).

Workstation and Accessories

The Workstation is a user-provided 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.

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 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.

Summary of Technological Characteristics

The PillCam SB 3 capsule endoscopy system and PillCam Software 9.0E components are identical to the components of the currently marketed predicate devices. Both the subject device and the primary and secondary predicate devices, use the same mechanisms to fulfil their identical intended use, respectively, and share the same technological characteristics. Each of the components of the subject device operates using the same technology and technological characteristics as the currently marketed predicate devices, respectively.

The only difference between the subject device and the currently marketed proposed predicates is a change to the labeling to allow remote administration of the subject device's SB 3 Capsule as an option.

A table comparing the key features of the subject and predicate devices is provided below.

Performance Data

Prior testing provided in support of the Given PillCam SB 3 capsule endoscopy system (K123864) and PillCam Desktop Software 9.0 (cleared in K170210 with SBC capsule endoscopy system), verified the device's components, as well as the performance. The subject device is almost identical to the currently marketed predicate devices; therefore, the previously completed non-clinical tests remain applicable.

The remote administration procedure has been performed at 3 commercial centers since October of 2020. At the time of this submission, 35 procedures have been performed with no complications reported. Additionally, usability testing was conducted in accordance with IEC 62366-1:2015 to evaluate the remote administration procedure of the device. This simulated-use testing consisted of simulated telehealth sessions with the device and a healthcare provider. The testing demonstrated that the device was easy to use and the HCP was able to instruct and monitor participants as needed during the procedure. No user-related hazards were recorded, with the errors captured not posing any additional risk.

Conclusions

The PillCam SB 3 Capsule endoscopy system with PillCam Software 9.0E is as safe and effective as the PillCam SB 3 endoscopy system (K123864), and the PillCam SBC capsule endoscopy system, PillCam Desktop Software 9.0 (K170210). The PillCam SB 3 capsule endoscopy system and PillCam Software 9.0E has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in the environment of use to incorporate the remote administration procedure do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled.

Table 1: Substantial Equivalence Table

	Subject Device	Predicate Devices	Comparison
Device Name	**PillCam SB 3 capsule endoscopy system and PillCam Software 9.0E (including Remote procedure)**	**PillCam SB 3 capsule endoscopy system with PillCam Software 9.0E (K123864, K170210)**	
Product Code	NEZ	NEZ, PGD	Similar
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.	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.	Identical*
Environment of Use	Inpatient, outpatient settings, remote use	Inpatient and outpatient settings	Similar
Obtained Parameters	images	images	Identical

	Subject Device	Predicate Devices	Comparison
Device Name	**PillCam SB 3 capsule endoscopy system and PillCam Software 9.0E (including Remote procedure)**	**PillCam SB 3 capsule endoscopy system with PillCam Software 9.0E (K123864, K170210)**	
System Components	Three main subsystems: PillCam SB capsules The PillCam DR3 Recorder The PillCam Software Workstation (WS) (supplied by the user) with PillCam Software Application (Version 9.0E)	Three main subsystems: PillCam SB capsules The PillCam DR3 Recorder The PillCam Software Workstation (WS) with PillCam Software Application (Version 9.0E)	Identical
Method of Removal	Natural excretion	Natural excretion	Identical
Capsule length	26.2 mm	26.2 mm	Identical
Capsule diameter	11.4 mm	11.4 mm	Identical
Weight	3.0 g	3.0 g	Identical
Material	Biocompatible plastic	Biocompatible plastic	Identical
Capsule Power Source Battery Type	2 Mercury free Silver Oxide batteries	2 Mercury free Silver Oxide batteries	Identical
# of optical heads	1	1	Identical
Optical Field of View	156 º (ISO-8600-3)	156 º (ISO-8600-3)	Identical
Signal Transmission	RF signal	RF signal	Identical
Effective Visibility Distance	0-30 mm	0-30 mm	Identical
Frame Rate	2 fps or 2 to 6 fps	2 fps or 2 to 6 fps	Identical
Operating Time	Minimum of 8 hours	Minimum of 8 hours	Identical
Imager	GILO6	GILO6	Identical
Number of pixels	320x320	320x320	Identical
Minimal detectable object	At least 0.07 mm	At least 0.07 mm	Identical
Programming of/and operation mode	Adaptive frame rate beginning at pairing	Adaptive frame rate beginning at pairing	Identical

*The full IFU statement of K170210 contains more statements due to the Colon Capsule, which is unrelated to the subject device. The only information of note is for the SB3.