May 10, 2024

Given Imaging Ltd. (d.b.a. Medtronic)
Aaron Niklaus
Sr. Regulatory Affairs Specialist
2 Hacarmel St. New Industrial Park
PO Box 258
Yoqneam Northern, 20692
Israel

Re: K240276
Trade/Device Name: PillCam™ Genius SB System with PillCam Software v9.7 and PillCam Cloud Reader Software
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: Class II
Product Code: NEZ
Dated: January 31, 2024
Received: January 31, 2024

Dear Aaron Niklaus:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240276

Device Name

PillCam™ Genius SB System with PillCam Software v9.7 and PillCam Cloud Reader Software

Indications for Use *(Describe)*

The PillCam™ Genius SB Capsule Endoscopy Kit with the PillCam Genius SB 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 PillCam Genius SB Capsule may be used as a tool in the detection of abnormalities of the small bowel and is intended for use 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.

510(k) SUMMARY

Given Imaging Ltd. (dba Medtronic Inc.)

PillCam™ Genius SB System with PillCam Software v9.7 and

PillCam Cloud Reader Software

Date Prepared: April 9, 2024

Submitter: Given Imaging Ltd. (d.b.a. Medtronic)
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Name of Device:

PillCam Genius SB System with PillCam Software v9.7 and 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 (including PillCam Cloud Reader Software) (K230991)

Device Description

The subject device introduces the PillCam Genius Capsule Endoscopy Kit (PillCam Genius SB Capsule and the PillCam Genius Link Device), the PillCam Genius Sync Agent, and the Real Time View Application.

The PillCam Genius Link Device is a single use device that is adhered to the patient's abdomen throughout the PillCam Genius SB procedure that connects to the PillCam Genius SB Capsule. Each Genius Link Device is paired and packaged with a single PillCam Genius SB Capsule. At the end of the procedure, the Link Device is removed and returned to the clinic.

The PillCam Genius Sync Agent is software used by the healthcare provider to setup and manage PillCam Genius SB endoscopy procedures and converts data from the PillCam Genius Link Device to the workstation.

The optional Real Time View Application allows the healthcare provider to view real time images from the capsule for a short period of time during the procedure to estimate the location of the capsule in the gastrointestinal tract.

The PillCam Desktop Software and HCP Software Application have been updated to display PillCam Genius SB Capsule procedures. The HCP Software Application has also been updated to be compatible with the PillCam Genius SB System and allow for uploading multiple procedures.

Intended Use/Indications for Use

The Subject Device has the same intended use and indications for use as the Predicate Device except for the removal of pediatric indications and removal of the optional SBI feature for PillCam Genius SB Capsule procedures.

Intended Use

The PillCam Genius SB Capsule Endoscopy Kit with the PillCam Genius SB Capsule is intended for visualization of the small bowel mucosa.

Indications for Use:

The PillCam Genius SB Capsule Endoscopy Kit with the PillCam Genius SB 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 PillCam Genius SB Capsule may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults.

Technological Characteristics

The Subject Device has similar technological characteristics when compared to the Predicate Device and any technological differences between the devices do not raise different questions of safety and effectiveness. The Subject Device has two main subsystems and one optional subsystem.

The introduction of new components replaces the functionality of some of the existing components, but the new components share similar technological characteristics.

The PillCam Genius Capsule is now sold with the PillCam Genius Link Device as the PillCam Genius SB Capsule Endoscopy Kit. The Genius Link Device has the receiving and recording functions of the Predicate Device's DR3 recorder. An optional Real Time View Application has been added to allow HCPs to view live images of the endoscopy procedure. The Genius Sync Agent converts capsule procedure data into a compiled format for the Desktop Software which had previously been done by the DR3 recorder. The Genius Sync Agent replaces the PillCam Sync Agent when used to synchronize between the PillCam Workstation and the PillCam Cloud Reader Software.

The Software Workstation and PillCam Cloud Reader Software retain the same functionality as the Predicate Device.

Principles of Operation

Both the Subject Device and the Predicate Device have the same principles of operation, where the receiver and capsule are paired, the patient places a receiver on their abdomen, ingests the capsule, and real-time images of the small bowel are obtained, which are then reviewed by an HCP.

Performance Testing

Biocompatibility Testing

Biocompatibility testing was conducted on the PillCam Genius Link Device in accordance with Guidance for Industry and FDA Staff "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'".

Bench Testing

Bench testing was conducted to demonstrate the safety and efficacy of the PillCam Genius Capsule Endoscopy Kit according to Guidance for Industry and FDA Staff "Ingestible Telemetric Gastrointestinal Capsule Imaging System - Final Class II Special Controls".

The PillCam Genius Capsule Endoscopy Kit passed the following tests:

- PH resistance
- Mechanical integrity
- Battery reliability
- Field of View (FOV) and Depth of Field
- Communication performance between capsule and recorder
- Adhesion on skin testing
- Environmental testing
- Usability testing

Animal Studies

No animal studies were conducted in support of this 510(k) submission.

Clinical Testing

No clinical testing was conducted in support of this 510(k) submission.

Electrical Safety and EMC

Electrical safety and EMC testing were performed on the PillCam Genius Capsule Endoscopy Kit. The system complies with IEC 60601-1 for safety and IEC 60601-1-2 for EMC.

Software Documentation

Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". The software documentation level for the Subject Device is considered basic as a failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

Conclusion

The conclusions drawn from the nonclinical testing demonstrates that the Subject Device is as safe, as effective, and performs as well as or better than the legally marketed Predicate Device.