DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2017

Given Imaging Ltd.
Hilla Debby
Director Clinical & Regulatory
2 Hacarmel St. New Industrial Park
POB 258
Yoqneam, 20692
Israel

Re: K170839
Trade/Device Name: RAPID Web
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: II
Product Code: NEZ, NSI, PGD
Dated: March 16, 2017
Received: March 21, 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 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 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,

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K170839

Device Name

RAPID Web

Indications for Use *(Describe)*

With PillCam SB 2 and SB 3 Capsules

The PillCam Capsule Endoscopy System with a PillCam SB 2 and SB 3 capsules is intended for visualization of the small bowel mucosa.

- PillCam Capsule Endoscopy System with PillCam SB 2 and SB 3 capsules may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- PillCam Capsule Endoscopy System with PillCam SB 2 and SB 3 capsules 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.
- PillCam Capsule Endoscopy System with PillCam SB 2 and SB 3 capsules 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 Capsule Endoscopy System with PillCam SB 2 and SB 3 capsules 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 ESO 3 Capsule

The PillCam Capsule Endoscopy System with PillCam ESO 3 capsules is intended for the visualization of esophageal mucosa in adults and children from 18 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 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.

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.(GI Solutions, Medtronic) 2 Hacarmel Street New Industrial Park PO Box 258 Yokneam 20692 Israel
Contact Person:	Hilla Debby Director, Clinical & Regulatory Email: Hilla.Debby@medtronic.com
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Fax Number:	972 (73) 2501533
Date Prepared:	March 16, 2017

II. DEVICE

Device Trade Name: RAPID Web

Common or Usual Name, Classification Name, Regulatory Class, and Product Code:

21 CFR 876.1300 Ingestible telemetric gastrointestinal capsule imaging system

21 CFR 876.1330 Colon capsule endoscopy system

NEZ – System, imaging, gastrointestinal, wireless, capsule, class II

NSI - System, imaging, esophageal, wireless, capsule, class II

PGD - colon capsule imaging system, class II

III. PREDICATE DEVICES

RAPID 8.0 Software (K123864)

Reference Devices: UGI Capsule (K140284) and COLON 2 Capsule (K153466)

IV. DEVICE DESCRIPTION

The RAPID Web is a client server based version of the RAPID video review and report creation components of the cleared RAPID 8 software. The RAPID Web is designed to allow users to review and analyze videos created using the cleared RAPID software, and to create reports over a private intranet network or over a secure internet connection. The PillCam capsule studies are created at workflow-relevant locations and stored at a central repository. The RAPID Web server is installed on a central server in an intranet or internet environment with access to the study repository. After the capsule endoscopy procedure was conducted using the cleared RAPID software, Given Workstation/User PC, PillCam capsule, and DR 3 PillCam recorder, end users will use an internet browser with authorization login to access, review, and manage the studies in the repository using workstation, user PC, a laptop or an Apple™ iPad™ (screen size > 9.7").

V. INTENDED USE / INDICATIONS FOR USE

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VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The RAPID Web and RAPID 8.0 have the same intended use and indications, and similar technological characteristics and principles of operation. The only technological differences between the RAPID Web and its predicates are: relocation of software from local hard drive to web-based server, increased range of viewing platforms, removal of features intended for use on mainframes and PCs, removal of viewing modes and features not critical to diagnosis, and the addition of several user friendly features. These differences do not present any new issues of safety or effectiveness because they are not critical to diagnosis and primarily affect convenience. Thus, the RAPID Web is substantially equivalent to the RAPID 8.0.

	RAPID Web (subject)	**RAPID 8.0 (K123864)**
Intended Use	Viewing of capsule endoscopy studies	Viewing of capsule endoscopy studies
Capsule endoscopy procedure (Check-in, initialization, video creation)	Not supported	Supported
Capsule endoscopy post-procedure steps (Video review and report creation)	Supported	Supported
Installation	Installed on a server	Installed on a work station

Hardware	Workstation, PC, laptops, Apple iPads > 9.7" screen	Workstation, PC
Main video reading features (Open, play, viewing modes, FICE & Blue	Supported	Supported
Workstation related features (keyboard, CD, etc.)	Not supported	Supported
Optional viewing aids (mosaic view, image enhancement control options, Lewis score, atlas, compare thumbnails etc.)	Not supported	Supported
Additional features (dynamic player control, findings preview)	Supported	Not Supported

Minimum Requirements

Minimum Display Requirements for Workstations Monitors

	Minimum Requirement
Diagonal	20"
Response time	8 ms
Advanced contrast	15,000:1
Resolution max	1600x900

Minimum Display Requirements for Laptops

	Minimum Requirement
Diagonal	12.5"
Static contrast	300:1
Brightness	200 nits
PPI	107 PPI
Resolution max	1366 x 768 1280 x 800
Refresh rate	60 Hz

Minimum Display Requirements for iPads

	Minimum Requirement
Diagonal	9.7"
Resolution max	264 PPI
Diagonal	2048 x 1536

Compatible operating systems and browsers:

1. For Windows 7 SP1, and Windows 8 or win 8.1:
   1.1. Chrome v38.
   1.2. Firefox v33.
   1.3. Internet Explorer 11.0.4.

   Hardware specifications: All Windows related tests were performed on Intel x86-based computer hardware that meets the operating system minimum requirements.

2. For MacOS v10.10 "Yosemite":
   2.1. Safari 8.0

3. For MacOS v10.8 "Mountain Lion" and v10.9 "Mavericks":
   3.1. Safari 7.1

   MAC Hardware specifications:
   - MacBook Pro 13", 2.4GHz dual-core Intel Core i5 processor, 4GB RAM
   - Macbook air 13", 1.8HGZ dual-core Intel Core i7, 4GB RAM

4. For iPad with iOS 8.1:
   4.1. Safari 8.0

   iPad Hardware specifications:
   - iPad 4: Dual-core A6X with quad-core graphics and 16GB storage
   - iPad air: A7 chip with 64-bit architecture and 16GB storage

5. Color depth: 24 bit

VII. PERFORMANCE DATA

A comparative performance study wherein trained professionals identified pathologies in the same video and video segments that we displayed using RAPID Web and RAPID 8.0 was performed. RAPID 8.0 performance was assessed on multiple platforms, including workstations, laptops, and iPads. An analysis assessing the matched and un-matched pathologies showed that RAPID 8.0 met the pre-specified sensitivity.

In addition, the software was validated and documented per FDA's software guidance document.

VIII. CONCLUSIONS

The RAPID Web is as safe and effective as the RAPID 8.0. The RAPID Web has the same intended uses and indications, and similar technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the RAPID Web and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the RAPID Web is as safe and effective as the RAPID 8.0. Thus, the RAPID Web is substantially equivalent.