



Given Imaging Limited
New Industrial Park
PO Box 258, Yoqneam
20692 Israel
Voice 972 4 909 7777
Fax 972 4 959 2466

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address: Given Imaging Ltd.
Hermon Building
New Industrial Park
PO Box 258
Yoqneam 20692
Israel
Tel.: 011-972-4-9097936
Fax: 011-972-4-9938060

Contact Person: Tim Thomas
SVP, Regulatory, Clinical, and Quality
Email: tim.thomas@givenimaging.com

Phone Number: 770-662-0870 ext. 1006

Fax Number: 770-662-0510

Establishment Registration Number: 9710107

Date Prepared: August 9, 2013

Device Trade Name(s): Given® PillCam® SB 3 capsule endoscopy system
Given® PillCam® endoscopy system with RAPID® 8.0

Device Common Name: Ingestible telemetric gastrointestinal capsule imaging system

Classification: Regulation No: 876.1300, Class: II
Panel: Gastroenterology/Urology
NEZ – System, Imaging, Gastrointestinal, Wireless, Capsule

Predicate Device(s):

- Given PillCam Platform with PillCam RAPID 6.5 (K103025)
- Given PillCam Platform System with PillCam SB Capsules (K101250)

AUG 12 2013



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General Device
Description:

The Given PillCam Endoscopy system is comprised of four main subsystems: (1) the ingestible PillCam capsule, (2) the DR 3 PillCam Recorder, (3) the RAPID software, and (4) the Given Workstation and Accessories.

1. *Ingestible PillCam Capsule*

The disposable, ingestible PillCam Capsule is designed to acquire video images during the natural propulsion through the GI tract. The capsule transmits the acquired images via a RF communication channel to the PillCam Recorder located outside the body.

2. *DR 3 PillCam Recorder*

The DR 3 PillCam Recorder is an external receiving/recording unit that receives and stores the acquired images from the capsule.

3. *RAPID Software*

The RAPID Software is a software application that is utilized to process, analyze, store, and view the acquired images collected from the PillCam Recorder to create a RAPID video of the images. The software also includes a reporting function to create detailed clinical reports, in-service training videos, and patient instruction forms.

RAPID 8.0 supports PillCam capsule endoscopy of the GI tract with all PillCam video capsules. In addition, RAPID 8.0 supports PillCam Recorder DR 2C and PillCam Recorder DR 3.

4. *Given Workstation and Accessories*

The Workstation is a modified standard personal computer that is the operational platform for the RAPID software. The PillCam Recorder is an external receiving/recording unit that receives acquired images from the capsule. The Sensor Array or Sensor Belt receives data from the PillCam capsule and transfers the data to the PillCam Recorder. The RAPID *Real Time* is a handheld device that allows for real-time viewing of acquired images through the GI tract. Other accessories include a flat panel LCD monitor, a high-capacity mass storage device, and a high-capacity USB portable storage device.



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Indication for use: **1. Given PillCam endoscopy system with RAPID 8.0**

With PillCam SB Capsule

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

The PillCam ESO capsule is intended for the visualization of esophageal mucosa.



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Technological Characteristics: The technological characteristics are similar to the predicate devices, except for the differences that are listed in Section 12 of this submission. However, it may be concluded from the Substantial Equivalence Summary that none of the presented differences raise any new safety or efficacy issues.

The primary improved features of PillCam SB 3 capsules are the capsule optical spatial resolution, to achieve better image quality, and higher effective and adaptive frame rate (AFR), to achieve better coverage of small bowel tissue in segments at which the capsule moves fast such as in the duodenum. The main new features implemented in PillCam recorder DR 3, are support of the new introduced SB 3 capsule and support of its functionalities such as: Real-time SB detection, Bi-directional communication and Adaptive Frame Rate (AFR) activation. The safety of PillCam SB 3 capsules was validated and no safety or efficacy issues have been raised. It may be concluded that the new features do not raise new safety issues.

Bench testing: Since PillCam SB 3 capsule and the predicate device are same capsules in terms of external components and technology. The biting test and pH resistance test for the predicate device are applicable for PillCam SB 3 capsules as well. Additional bench testing included field of view (FOV), battery life, wireless communication, color reproduction, image quality, frame rate verification, and optical resolution.

Performance Data: The devices meet the guidance entitled "*Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA* dated November 28, 2001.

The Given PillCam endoscopy system with RAPID 8.0 was validated with clinical data. The Advanced A-Mode software feature was also validated with clinical data. The proposed changes in this submission do not raise new performance or safety issues.

Conclusion: Based on the technological characteristics of the devices, Given Imaging Ltd. believes that the Given PillCam endoscopy system with RAPID 8.0 and Given PillCam SB 3 capsule endoscopy system and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.



August 12, 2013

Given Imaging, Ltd.
% Tim Thomas
Senior Vice President
Hermon Building New Industrial Park, P.O. Box 258
Yokneam 20692
Israel

Re: K123864
Trade/Device Name: Given PillCam endoscopy system with RAPID 8.0
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ
Dated: July 11, 2013
Received: July 15, 2013

Dear Tim Thomas:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert P. Lerner - 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

INDICATIONS FOR USE

510(k) Number : K123864

Device Name: Given PillCam endoscopy system with RAPID 8.0

Indications for Use:

With PillCam SB Capsule

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- 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 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 ESO Capsule

The PillCam capsule endoscopy system with PillCam ESO capsules is intended for the visualization of esophageal mucosa.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

Given Imaging Ltd. K123864 – Response Letter
PillCam® SB 3 capsule endoscopy system
Supplement #1
April 28, 2013

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K123864