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

SEP 2 8 2009

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.: 011-972-4-9097730 Fax: 011-972-4-9938060
Contact Person:	Tim Thomas Global Director, Regulatory 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:	February 23, 2009
Device Trade Name(s):	Given PillCam® Platform with PillCam® SB Capsules Given® AGILE Patency System
Device Common Name:	Ingestible telemetric gastrointestinal capsule imaging system
Classification:	Regulation No: 876.1300 Class: II Panel: Gastroenterology NEZ – System, Imaging, Gastrointestinal, Wireless, Capsule NSI – System, Imaging, Esophageal, Wireless, Capsule
Predicate Device(s):	Given® Diagnostic System with PillCam® SB2 Capsule (K070475) Given® AGILE Patency System (K053639)

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

General Device Description:

The Given PillCam® Platform is comprised of three main subsystems; (1) the ingestible PillCam capsule, (2) the RAPID® software, and (3) the Given® Workstation and Hardware.

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 DataRecorder located outside the body.

2 RAPID Software

The RAPID Software is a software application that is utilized to process, analyze, store, and view the acquired images collected from the DataRecorder 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.

3 Given Workstation and Hardware

The Workstation is a modified standard personal computer that is the operational platform for the RAPID software. The DataRecorder is an external receiving/recording unit that receives acquired images from the capsule. The SensorArray receives data from the PillCam capsule and transfers the data to the DataRecorder. 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.

The Given Agile Patency System is designed to determine which patients with known or suspected intestinal strictures can safely ingest a PillCam video capsule. The system consists of an ingestible and dissolvable capsule that is the same size as the PillCam SB capsule, and an external scanner.

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

Intended Use:	SB Indications for Use: The Given PillCam® Platform with the PillCam® SB Capsules is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age. The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas. AGILE Indications for Use: The Given® AGILE Patency System is an accessory to the PillCam video capsule and is intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures in adults and children from two years of age.
Technological Characteristics:	The technology characteristics are exactly the same as the predicate devices.
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. Clinical data has been summarized to show safety and effectiveness for the proposed indications for use.
Conclusion:	Based on the technological characteristics and clinical performance of the devices, Given Imaging Ltd. believes that the Given PillCam® Platform with PillCam® SB Capsules, the Given® AGILE Patency System and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Tim Thomas
Global Director, Regulatory and Quality
Given Imaging Limited
New Industrial Park, PO Box 258
Yoqneam, 20692
ISRAEL

SEP 2 8 2009

Re: K090557
Trade/Device Name: Given® AGILE Patency System and Given PillCam® Platform with PillCam® SB Capsules
Regulation Number: 21 CFR 876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ, NSI
Dated: September 13, 2009
Received: September 15, 2009

Dear Mr. 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.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090557

Device Name: Given® AGILE Patency System

Indications for Use:

AGILE Indications for Use:

The Given® AGILE Patency System is an accessory to the PillCam video capsule and is intended to verify adequate patency of the gastrointestinal tract prior to administration of the PillCam video capsule in patients with known or suspected strictures in adults and children from two years of age.

Prescription Use ✓ 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090557

INDICATIONS FOR USE

510(k) Number (if known): K090557

Device Name: Given PillCam® Platform with PillCam® SB Capsules

Indications for Use:

SB Indications for Use:

The Given PillCam® Platform with the PillCam® SB Capsules is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age.

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

Prescription Use ✓ 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)

510(k) Number (if known): _____

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090557