MAY - 8 2006

510(K) SUMMARY

Given® AGILE Patency System

510(k) Number K K053639 .

Applicant's Name:

Given Imaging Ltd.
Hermon Building (Shaar Yoqneam)
P.O. Box 258
New Industrial Zone
Yokneam 20692, Israel
Tel.: 011-972-4-9097730
Fax: 011-972-4-9592466

Contact Person:

Shosh Friedman, RAC
Senior V.P. Regulatory & Clinical Affairs
Tel: 011-972-4- 909 7784
Fax: 011-972-4-993 8060
Email: shosh@givenimaging.com

Trade Name:

Given® AGILE Patency System (an optional accessory to the Given® Diagnostic System with PillCam Capsules)

Classification Name:

Ingestible Telemetric Gastrointestinal Capsule Imaging System

Classification:

FDA has classified Ingestible Telemetric Gastrointestinal Capsule Imaging System as class II devices (product code 78NZE and 78NSI) and they are reviewed by the Gastroenterology Panel.

Predicate Device:

The Given AGILE Patency System is an accessory for the Given® Diagnostic System with PillCam™ Capsules (Given Imaging Ltd.) cleared under K010312, K020341, K022362, K022980, K031033, K032405, K040248, K041149, K042960, and K052184.

Intended 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.

Device Description:

The Given® AGILE Patency System is a simple and easy to use device for verifying the patency of the GI tract. It consists of the following components:

- Given AGILE Patency capsule
- Given AGILE Patency Scanner
- TesTag (interference tester)

Once the patient ingests the Given AGILE Patency capsule it is propelled through the GI tract by normal peristalsis. If the AGILE Patency capsule is excreted structurally whole, then this indicates patency of the GI tract of the patient and a PillCam capsule can be administered. The capsule is designed to dissolve starting 30 hours following ingestion, during a period of approximately 12 hours. If anytime before 30 hours after capsule ingestion the AGILE Patency capsule cannot be detected in the patient's body by the Given AGILE Patency Scanner, it indicates that the GI tract is patent and that the capsule was excreted naturally.

The Given AGILE Patency Scanner is used to detect the presence of the Given AGILE Patency capsule in the patient's body. If a scanner is not available, or if localization of a retained capsule is desired, fluoroscopy can be used.

If the Given AGILE Patency Scanner detects the Given AGILE Patency capsule in the GI tract 30 hours post-ingestion, then patency of the GI tract is not indicated. Eventually, the capsule dissolves into small fragments and is naturally excreted.

Substantial Equivalence:

Given Imaging Ltd. believes that, based on the information provided in the submission, the Given® AGILE Patency System is substantially equivalent to its predicate devices without raising any new safety and/or efficacy issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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Shoshana Friedman, RAC
Senior VP, Regulatory and Clinical Affairs
Given Imaging Ltd.
Hermon Building (Shaar Yoqneam)
PO Box 258
New Industrial Zone
Yokneam 20692
ISRAEL

Re: K053639
Trade/Device Name: Given® AGILE Patency System
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NSI and NEZ
Dated: April 26, 2006
Received: May 1, 2006

Dear Ms. Friedman:

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 (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053639 .

Device Name:

Given® AGILE Patency System

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.

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

510(k) Number K053639 .

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

David A Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053639