NOV 2 4 2004

510(K) SUMMARY

Given® Diagnostic System with PillCam™ ESO Capsule

510(k) Number K042960

Applicant's Name:

Given Imaging Ltd.
13 HaYetzira St.
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
Corporate V.P. Regulatory & Medical Affairs
Tel: 011-972-4- 9097784
Fax: 011-972-4-9938060
Email: shosh@givenimaging.com

Trade Name:

Given® Diagnostic System

Classification Name:

Ingestible Telemetric Gastrointestinal Capsule Imaging System

Classification:

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

Predicate Device:

Given® Diagnostic System with PillCam™ (M2A®) ESO Capsule (K041149)

Performance Standards and Special Controls:

The Given® Diagnostic System complies with the requirements presented in "Class II Special Controls Guidance Document; Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA" issued on November 28,2001

Intended Use:

The Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa.

Device Description:

The Given® Diagnostic System with the PillCam™ ESO Capsule is comprised of three subsystems: PillCam™ ESO Capsule, Data Recorder Set, and RAPID® Workstation.

The PillCam™ ESO Capsule is a wireless, disposable capsule designed to glide smoothly through the esophagus. During its passage, the capsule transmits digital data that is captured by receiving antennas attached to the patient's body. The images are stored in the DataRecorder that is connected to the receiving antennas and is worn on a belt around the waist of the patient. When the test is over, the antennas and recorder are removed from the patient's body. The images from the recorder are downloaded to the RAPID® Workstation for processing and viewing by the physician.

The reason for this submission is the implementation of two modifications in the system: (1) improved capsule model that transmits images at a rate of 14 frames per second (fps); and (2) release of an improved version of the RAPID Software application.

Substantial Equivalence:

Given Imaging Ltd. believes that, based on the information provided in this submission, the Given® Diagnostic System with PillCam™ ESO Capsule is substantially equivalent to the market-cleared Given® Diagnostic System with the PillCam™ ESO Capsule without raising any new safety and/or efficacy issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shosh Friedman, RAC
Corporate V.P. Regulatory & Medical Affairs
Given Imaging Ltd.
13 HaYetzira Street, P.O. Box 258
New Industrial Zone
Yoqneam 20692
ISRAEL

Re: K042960
Trade/Device Name: Given® Diagnostic System with PillCam™ ESO
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: 78 NSI
Dated: October 10, 2004
Received: October 27, 2004

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/dsma/dsmamain.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

ATTACHMENT 6-3

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K04 2960

Device Name:

Given® Diagnostic System with PillCam™ ESO Capsule

Indications for Use:

The Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa.

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

510(k) Number K042960

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042960