

MAY 18 2012

### 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

#### 1. Company and Correspondent making the submission

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Internet	<a href="http://www.intromedic.com">http://www.intromedic.com</a>

#### 2. Device

Proprietary Name	MiroCam® Capsule Endoscope System
Common Name	Capsule Imaging System
Classification Name	21 CFR 876.1300 (Product Code NEZ)

#### 3. Predicate Device

Manufacturer	Given Imaging Ltd.
Device	Given Diagnostic Imaging System
510(K) Number	K070475

#### 4. Description

The MiroCam® Capsule Endoscope System is comprised of the following core components:

- MiroCam® Capsule
- Data Cables
- MiroCam® Receiver
- MiroView™ Software and Workstation

The general usage workflow of the MiroCam® system is as follows, the MiroCam® capsule captures images of the GI tract, which are sent via Human Body Communication to sensor pads which are affixed to the patient body. The sensor pads are connected to the receiver by the data cables. The image data is stored on the receiver for the duration of the patient procedure. After removing the receiver set from the patient body, the receiver is connected via USB to the MiroView™ workstation and the image data is uploaded. Following upload, the physician (Gastroenterologist) reviews the patient image data for suspected abnormalities of the small bowel. The key system components are explained in detail below.

#### MiroCam® Capsule

Functionally, the MiroCam® capsule captures imaging via a CMOS imaging sensor for at least 11 hours at the rate of 3 images per second. Six white LEDs flash in concert with the imaging sensor. A sensor PCB links the imaging sensor to the two gold electrodes of the capsule, from which a weak current is emitted containing the image data via Human Body Communication technology. The weak current is then passed through the bodily tissue and fluid to be picked up by the sensor pads. Human Body Communications is uni-directional from the capsule to the sensor pads.

Physically, the capsule is 24mm in length, and 10.8mm in diameter. The exterior of the capsule is composed of biocompatible materials, capable of withstanding potential bite forces and exposure to fluids in the GI tract.

#### MiroCam® Receiver

The image data from the capsule is saved to the MiroCam® Receiver via the sensor pads and data cables. The sensor pads are standard ECG type sensor pads (3M Red Dot), which are affixed to the patient's abdomen according to the location guide. The 9 sensor pads are attached to the 9 leads of the data cable, and the data cable is subsequently attached to the Receiver. The Receiver sits in a shoulder pouch, which is put on the patient for the duration of the procedure. A waist pouch is used to organize the data cables. The Receiver can store images for up to 12 hours. The three indicators on the Receiver are for battery status, initialization status of the receiver, and status of signal receipt from the capsule.

The dimensions of the receiver are 140mm in height, 85mm in width, and 40mm in length. The units weight 350grams with the battery, which is data cable. The battery is lithium ion,

and is unique to the Receiver. The battery is rechargeable, and can be charged by placing in the battery charger provided with the Receiver. The receiver uses a storage flash for storing the images.

#### Workstation

Image data is uploaded to the MiroView™ workstation from the MiroCam® Receiver via a USB cable connection. The MiroView™ workstation is a PC with the MiroView™ software installed. The workstation also includes a printer and LCD monitor.

The MiroView™ software enables the following key operator tasks: receiver management and upload of image data; diagnostic review of images by the physician; creation of capsule endoscopy procedure patient reports; user administration; and export of image data and reports. Included in the diagnostic review interface is a number of features to optimize the efficiency of the diagnostic review, including variable viewing speed (1 to 40 frames per second), suspected GI bleeding indicator (SGIB), and Quick mode. Images of suspected disease pathology or transit points in the GI tract are readily captured for inclusion in the report.

Included with the MiroView™ workstation is a copy of MiroView™ Express. MiroView™ Express is a scaled down version of the MiroView™ software; only supporting the diagnostic review and reporting functionality detailed above. The receiver cannot be connected to the MiroView™ Express software. This software can be installed on remote PCs, notebooks or laptops to enable review of patient files at the convenience of the reviewer. Patient files are transferred from MiroView™ workstation to the MiroView™ Express via DVD or USB.

#### **5. Indications for Use**

The MiroCam® Capsule Endoscope System 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.

The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.

## 6. Technological Characteristics and Substantial Equivalence

The characteristics of the IntroMedic Co., Ltd. MiroCam® Capsule Endoscope System are substantially equivalent to the following current legally marketed predicate devices based on indications for use, typical clinical use, and operational and fundamental technological characteristics

- Given Diagnostic Imaging Systems marketed by Given Imaging Ltd., K070475

A detailed side-by-side comparison of the MiroCam® Capsule Endoscope System with the identified predicate device is provided in the substantial equivalence discussion in this premarket notification.

## 7. Performance Testing

The MiroCam® Capsule Endoscope System performance testing includes biocompatibility testing, electrical safety testing, and software life cycle validation to the appropriate FDA Recognized Consensus Standards and bench testing which includes mechanical structural integrity testing, pH resistance testing, field of view and depth of view testing, battery life testing, and battery short-circuit temperature testing. The results of this performance testing conclude that the material and technological characteristics have not diminished the safety and effectiveness of the IntroMedic Co., Ltd. MiroCam® Capsule Endoscope System device when compared to the predicate device.

A multi-center, prospective, randomized, open-label clinical trial was performed on the MiroCam® Capsule Endoscope System. The effectiveness endpoint was to compare the agreement between MiroCam® and predicate device with respect to the detection and identification of sources of small bowel bleeding. The concordance rate and corresponding 95% confidence interval were estimated. The 89 of the 105 subjects were evaluable for the effectiveness analysis, having at least 2 hours of small bowel imaging time successfully. The overall agreement on the identification (cause) of small bowel bleeding between MiroCam® and predicate device was 74.16% (66 of 79). The results of this clinical testing conclude that the IntroMedic Co., Ltd. MiroCam® Capsule Endoscope System is safe, performs as intended, and meets the user needs.

**8. Conclusion**

Based on the similarities in indications for use, design, functional, and operational features as evaluated through clinical and non-clinical performance testing the IntroMedic Co., Ltd. MiroCam® Capsule Endoscope System has demonstrated substantial equivalence to the listed legally marketed predicate devices and any differences do not affect the product's safety or effectiveness.

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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

IntroMedic Co., Ltd.  
% Mr. Jeffrey Roberts  
Regulatory Consultant  
Medical Device Consultants, Inc.  
40 Plain Street  
NORTH ATTLEBORO MA 02760

MAY 18 2012

Re: K111450  
Trade/Device Name: MiroCam® Capsule Endoscope System  
Regulation Number: 21 CFR§ 876.1300  
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system  
Regulatory Class: II  
Product Code: NEZ  
Dated: May 14, 2012  
Received: May 16, 2012

Dear Mr. Roberts:

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.

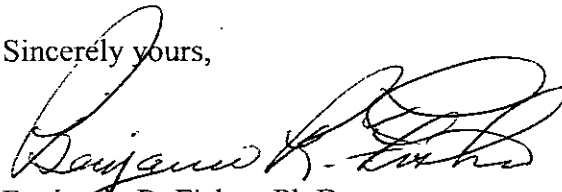
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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 (if known): K111450

Device Name: MiroCam® Capsule Endoscope System

Indications for Use:

**MiroCam® Capsule Endoscope System** 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.

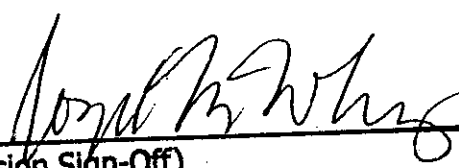
The Suspected GI Bleeding Indicator (SGIB) is intended to mark frames of the video suspected of containing blood or red areas.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

  
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(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K111450

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