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510(k) Summary

DEC 1 2010

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.

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Contact Person:	Tim Thomas Vice President, Regulatory Affairs and Quality Assurance Email: tim.thomas@givenimaging.com
Phone Number:	770-662-0870 ext. 1006
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Establishment Registration Number:	9710107
Date Prepared:	September 1, 2010
Device Trade Name(s):	Bravo pH Monitoring System™ and Accessories
Device Common Name:	Stomach pH electrode
Classification:	Regulation No: 876.1400 Class: I Panel: Gastroenterology FFT - Stomach pH electrode
Predicate Device(s):	Bravo pH Monitoring System™ and Accessories (K002028)
General Device Description:	The Bravo pH Monitoring System™ and Accessories is an ambulatory esophageal pH testing device.

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The Bravo system is a simple, minimally invasive outpatient procedure that involves the placement of a pH telemetry Capsule against the mucosal wall of the esophagus that simultaneously measures pH and transmits the data to a receiver attached to the patient's waist.

The Bravo pH Monitoring System™ and Accessories consists of four main components:

Bravo pH Capsule with Delivery System

Bravo pH Capsule with Delivery System is an antimony pH sensor, in the form of a pH Capsule that is temporarily attached to the wall of the esophagus with a delivery system. The capsule is placed following an esophago- gastroduodenoscopy (EGD) at 6 cm above the Z-line. The capsule then transmits pH data via radiotelemetry to a receiver worn by the patient.

Bravo pH Receiver

The Bravo pH Receiver is lightweight and compact. It fits into a carrying case that comes with a strap and a belt clip allowing patients to carry it over the shoulder, attach it to a belt, or carry it in a pocket (without the carrying case). This flexibility allows the patient to carry the Receiver throughout the study period. The Receiver is designed with two separate interfaces: one for the patient and one for clinicians.

RAPID pH and PolygramNet software

The software is intended to record, store, view, and analyze gastroesophageal pH data, enabling physicians to interpret study results.

Bravo pH Delivery System Accessories:

Bravo pH Delivery System Accessories include calibration stand, vacuum pump, pH 1.07 and pH 7.01 calibration buffer solutions, Bravo DataLink, Bravo Adapter, and Bravo Pouch.

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Intended Use:	The Bravo pH Monitoring System is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age. The Bravo pH Capsule can be attached following either endoscopy or manometry. The RAPID pH software is intended to record, store, view, and analyze gastroesophageal pH data.
Technological Characteristics:	The technology characteristics are exactly the same as the predicate devices.
Performance Data:	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 Bravo pH Monitoring System™ and Accessories and the predicate device selected is substantially equivalent and does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Tim Thomas
Vice President
Regulatory Affairs and Quality Assurance
Given Imaging Limited
New Industrial Park
P.O. Box 258, Yoqneam 20692
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DEC 1 2010

Re: K102543
Trade/Device Name: Bravo pH Monitoring System™ and Accessories
Regulation Number: 21 CFR §876.1400
Regulation Name: Stomach pH electrode
Regulatory Class: I
Dated: September 1, 2010
Received: September 3, 2010

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. 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, M.D., Director (Acting)
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): K102543

Device Name: Bravo pH Monitoring System™ and Accessories

DEC 1 2010

Indications for Use:

The Bravo pH Monitoring System is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age. The Bravo pH Capsule can be attached following either endoscopy or manometry. The RAPID pH software is intended to record, store, view, and analyze gastroesophageal pH data.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102543