DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Kathleen H. Selover
Director, Regulatory Affairs and Quality
The SmartPill Corporation
847 Main Street
Buffalo, New York 14203-1109

JAN 10 2017

Re: K053547
Trade/Device Name: SmartPill GI Monitoring System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: NYV
Dated: May 18, 2006
Received: May 18, 2006

Dear Ms. Selover:

This letter corrects our substantially equivalent letter of July 18, 2006.

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 Parts 801 and 809); 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 Parts 801 and 809]), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

Benjamin 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 STATEMENT

510(k) Number, if known: K053547

Device Name: SmartPill GI Monitoring System

Indications for Use:

The SmartPill GI Monitoring System is indicated for use in evaluating patients with suspected delayed gastric emptying (gastroparesis).

The SmartPill GI Monitoring System measures pH, pressure and temperature throughout the gastrointestinal tract. These physiological measurements are used to determine gastric emptying time (GET), total transit time (TTT), and combined small-large bowel transit time (SLBTT). In addition, pressure contraction patterns from the antrum and duodenum are used to calculate motility indices.

Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.

Not for use in pediatric populations

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-the-Counter Use _____ (Per 21CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053547

JUL 18 2006

510(K) SUMMARY
K053547

DATE OF SUMMARY:	July 7, 2006
MANUFACTURER:	The SmartPill Corporation 847 Main Street Buffalo, NY 14203
CONTACT INFORMATION:	Phone: 716.882.0701, ext. 106 Fax: 716.882.0706 Fax Email: kselover@smartpillcorp.com
CONTACT PERSON:	Kathleen H. Selover Director, Regulatory Affairs
DEVICE TRADE NAME:	SmartPill GI Monitoring System
DEVICE COMMON NAME:	Gastrointestinal pH and pressure monitoring equipment
CLASSIFICATION NAME, REGULATORY REFERENCE AND PRODUCT CODE	Unclassified Product Code: 78 NYV
PREDICATE DEVICE(S)	• Heidelberg pH Capsule and the Heidelberg Gold Medallion Gastro-intestinal pH Measurement System • Unisensor UniTip Gastrointestinal Pressure Catheter

PRODUCT DESCRIPTION

The SmartPill GI Monitoring System senses and records pH and pressure measurements from the entire length of the gastrointestinal tract for use by physicians to evaluate patients with delayed gastric emptying. Sensors on board an ingestible capsule measure pH and pressure as the capsule travels the length of the GI tract. Measurements are transmitted from the capsule within the GI tract via ASK modulated RF signal at 434 MHz to a patient-worn Data Receiver and subsequently downloaded to PC for analysis and review. MotiliGI™ Software performs data analyses automatically and provides the physician with a printable report containing gastric emptying time, motility index, and total transit time.

INTENDED USE INDICATIONS FOR USE

The SmartPill GI Monitoring System is indicated for use in evaluating patients with suspected delayed gastric emptying (gastroparesis).

The SmartPill GI Monitoring System measures pH, pressure and temperature throughout the gastrointestinal tract. These physiological measurements are used to determine gastric emptying time (GET), total transit time (TTT), and combined small-large bowel transit time (SLBTT). In addition, pressure contraction patterns from the antrum and duodenum are used to calculate motility indices.

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Not for use in pediatric populations

PHYSICAL AND TECHNICAL COMPARISONS	The SmartPill GI Monitoring System, as it applies to pH measurements, is the same as the intended use of the predicate, Heidelberg pH capsule and Monitoring System. Both devices use an ingestible capsule capable of measuring pH throughout the GI tract to provide a continuous data stream of measured pH values. The device is technically comparable to UniSensor UniTop pressure catheter. Both use a solid state piezo resistive pressure sensor for sensing pressure in the gastrointestinal tract and transmit the sensed signal to a receiving device. Display of contractile patterns are similar.
PERFORMANCE SUMMARY	The SmartPill GI Monitoring System was tested in multiple bench tests to verify the accuracy and precision of the device. In addition, clinical testing was conducted to validate the device's indications for use. Results of these tests support the product's intended use, indications for use, performance and clinical claims.
SAFETY TESTING	
BIOCOMPATIBILITY	All patient contacting materials were tested for biocompatibility in accordance with ISO-10993, Part I for a surface device that contacts breached or compromised surfaces for prolonged contact and plastic materials in accordance with USP <661>.
ELECTRICAL SAFETY	Electrical safety was conducted and found to meet the requirements of IEC 60601-1
ELECTROMAGNETIC COMPATIBILITY	EMC testing was tested and found to meet the requirements of IEC 60601-1-2