

JUL 18 2006

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**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.

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

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 18 2006

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

Re: K053547
Trade/Device Name: SmartPill GI Monitoring System
Regulatory Class: Unclassified
Regulation Number: None
Product Code: NYV
Dated: May 18, 2006
Received: May 19, 2006

Dear Ms. Selover:

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.



Protecting and Promoting Public Health

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.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

5/17/2006

SECTION 16

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