MAR 2 9 2012

5.0 510(k) Summary

Submitter:	Medspira 2718 Summer Street NE Minneapolis, MN 55413
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Date Prepared:	October 28, 2011
Trade Name:	mcompass™ Anorectal Manometry System
Common Name:	Gastrointestinal monitoring system
Classification:	Class II, Gastrointestinal motility monitoring system (21 CFR 876.1725)
Product Code:	KLA
Predicate Device(s):	• Latitude Ano-Rectal Pressure Catheter (K022023) • Latitude Directional Anorectal Manometry Catheter (510(k) number not available) • uroNIRS 2000 (K082701) • Manoscan 360AR (K031169)
Device Description:	The mcompass device is a manometry system for the measurement of anorectal pressures. It is used in a clinical setting and consists of a non-sterile disposable catheter, a reusable RMD FOB, and software that resides on a tablet PC that collects, records and displays data. During the clinical procedure, the distal end of the catheter is inserted in the anus/rectum of the patient. The proximal end of the catheter is connected via an integrated cable to the handheld RMD FOB which transmits real-time pressure data wirelessly to the mcompass software on the PC. Pressures are measured via four small, air-charged, radial balloons evenly spaced around the distal circumference of the catheter and a fifth larger balloon, positioned near the distal tip. The four small balloons measure radial contractile pressures of the anorectal canal while the most distal balloon is used to simulate a range of bowel fullness levels, in addition to measuring locational pressure.
Intended Use:	The mcompass Anorectal Manometry System is for use on patients requiring anorectal pressure studies.

Functional and Safety Testing:	To verify that device design met it's functional and performance requirements, representative samples of the device underwent mechanical, electrical, and biocompatibility testing in accordance with the applicable industry standards listed below: • ISO 10993-5 (2009) Biological Evaluation of Medical Devices - Part 5: Tests for Vitro Cytotoxicity • ISO 10993-12 (2007) Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials • ISO 10993-10 (2010) Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization • ISO 10993-11 (2006) Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity • EN 60601-1-2 (2001) Medical Electrical Equipment – Part 1:General Requirements for Safety, 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests • IEC 60601-1 (1988) Medical electrical equipment - Part 1: general requirements for safety (+A1:1991 and A2:1995) • EN 60601-1-4 (2000) Medical Electrical Equipment – Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems
Conclusion:	The information submitted in this premarket notification supports the determination that the Medspira mcompass Anorectal Manometry System is substantially equivalent in principles of operation, technology, materials and indications for use to the predicate devices listed above.

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

Medspira, LLC
% Mr. William Sammons
Sr. Project Engineer, Sr. Reviewer – Medical Devices
Intertek Testing Services
2307 East Aurora Rd. Unit B7
TWINSBURG OH 44087

MAR 29 2012

Re: K120088
Trade/Device Name: mcompass™ Anorectal Manometry System
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: KLA
Dated: March 9, 2012
Received: March 14, 2012

Dear Mr. Sammons:

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

4.0 Indications for Use Statement

Device Name: mcompass™ Anorectal Manometry System

Indications for Use:

The mcompass Anorectal Manometry System is for use on patients requiring anorectal pressure studies.

Prescription Use __X____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K120088