December 5, 2025

Medspira LLC
℅ Melinda Swanson
Regulatory Consultant
Bluebird Consulting LLC
301 Sugarbush Ln
Elkhart Lake, Wisconsin 53020

Re: K252605
Trade/Device Name: mcompass Anorectal Balloon Expulsion Catheter (RMD-003-001)
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: FFX
Dated: November 11, 2025
Received: November 12, 2025

Dear Melinda Swanson:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA, Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252605

Device Name

mcompass Anorectal Balloon Expulsion Catheter (RMD-003-001)

Indications for Use *(Describe)*

Use of the mcompass® Anorectal Balloon Expulsion Catheter is indicated when there is a need or suspicion of an anorectal disorder.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K252605

510(k) Summary

Prepared on: 2025-11-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medspira LLC
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Correspondent Address	301 Sugarbush Ln Elkhart Lake WI 53020 United States
Correspondent Contact Telephone	612-308-4500
Correspondent Contact	Ms. Melinda Swanson
Correspondent Contact Email	Melinda@bluebirddevice.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	mcompass Anorectal Balloon Expulsion Catheter (RMD-003-001)
Common Name	Gastrointestinal motility monitoring system
Classification Name	System, Gastrointestinal Motility (Electrical)
Regulation Number	876.1725
Product Code(s)	FFX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K823701	SR2B Single-Use PVC Manometric Catheter (Anorectal Balloon Expulsion - Air/Water)	FFX
K143031	mcompass Biofeedback Anorectal Catheter	KLA

Device Description Summary

21 CFR 807.92(a)(4)

Device Description Summary

The mcompass® Anorectal Balloon Expulsion Catheter is used to perform a Balloon Expulsion Test (BET) to evaluate a patient's recto-anal functionality and coordination by simulating the presence of feces to evaluate muscular contractions of the rectum. Use of the mcompass® Anorectal Balloon Expulsion Catheter is indicated when there is a need or suspicion of an anorectal disorder.

The catheter is ~60cm in length and constructed as a single-lumen flexible shaft with an expandable balloon on the distal end and a

stopcock for a closing mechanism on the proximal end. The shaft and balloon of the device is made of medical grade silicone rubbers.

The device is packaged and labeled as a single-use, non-sterile, disposable product.

BETs may be performed as a standalone test but are routinely performed along with an anorectal manometry examination. Procedurally, an empty and well lubricated anorectal balloon expulsion catheter is inserted into the rectum. A syringe with a luer end is filled with the desired volume of air or water, commonly 50-60 cc for adults, and connected to the catheter's luer fitting. The air or water is injected into the catheter causing the balloon to expand and simulate the presence of feces. The patient is sat on a toilet or commode and instructed to expel the balloon within a determined timeframe, often 60 seconds. The choice of air or water, volume of fill, and the timeframe for expulsion are at the discretion of the user.

Functionally, distention of the rectum, by balloon or feces, exerts pressure on the rectal wall which causes an autonomous nervous reflex response called the RectoAnal Inhibitory Reflex (RAIR). This involuntary reflex relaxes the internal anal sphincter, allowing for normal defecation.

The design of the mcompass® Anorectal Balloon Expulsion Catheter, including a firm yet pliable balloon, provides for meaningful distention at usual fill volumes to properly trigger RAIR and allow for normal expulsion by the patient, as if feces, for purposes of the BET.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Use of the mcompass® Anorectal Balloon Expulsion Catheter is indicated when there is a need or suspicion of an anorectal disorder.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical to the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The basic designs of all anorectal balloon expulsion catheters are both simple and highly similar. They are constructed as a single-lumen flexible shaft with an expandable balloon on the distal end and a closing mechanism such as a stopcock on the proximal end. Although some materials used by manufacturers are different from one catheter model to another, and are such between the Medspira catheter and that of its predicate (Mui Scientific SR2B), the overall design is the same.

The catheter's balloon is filled by syringe with either air or water to inflate the balloon and distend the rectum which triggers a Rectoanal Inhibitory Reflex (RAIR) event. RAIR is an involuntary reflex which causes the internal anal sphincter to relax in response to rectal distention.

The patient is instructed to expel the balloon as they would feces to evaluate the capability and coordination of applied rectal muscular pressure and relaxation of anal sphincter pressure allowing for normal defecation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Bench tests were performed to evaluate and compare device functional and physical characteristics including:
- Physical dimension or the catheters and their components
- Physical dimension of the balloons at various fill volumes
- Ability to maintain fill volumes for a defined duration

Bench tests were performed to evaluate and compare device performance characteristics including:
- Physical dimensions of the balloons at various fill volumes (both air & water)
- Ability to maintain fill volumes for a defined duration (both air & water)
- Back pressure at different fill volumes (both air & water)
-Expulsion through an orifice
-Static tensile force
-Kink stability - stiffness

Not Applicable

As described in RP-2103019-01, Substantial Equivalence Evaluation, Medspira believes there is substantial equivalence between the two devices, Mui Scientific SR2B and Medspira mcompass® RMD-003-001, and that the Medspira device will allow users to properly perform the procedures which the devices are intended for, with equivalent safety and effectiveness.