



September 30, 2026

Mui Scientific, Inc.
Fatemeh Rahimi
Quality and Regulatory Affairs Manager
145 Traders Blvd. E.,
Unit #34
Mississauga, Ontario L4Z 3L3
Canada

Re: K262621

Trade/Device Name: Rapid Barostat Bag (RBB) Pump and Catheter System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: Class II
Product Code: FFX
Dated: September 4, 2026
Received: September 4, 2026

Dear Fatemeh Rahimi:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MAURA ROONEY -S

for

Anthony C. Lee, Ph.D., M.B.A.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262621

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Please provide the device trade name(s).

?

Rapid Barostat Bag (RBB) Pump and Catheter System

Please provide your Indications for Use below.

?

The Rapid Barostat Bag Pump and Catheter are used together for the inflation of a barostat balloon to measure rectal capacity, as well as rectal volume at points of sensation, urge, and discomfort, to determine hypersensitivity, hyposensitivity, or normal rectal sensations. These determinations aid in the diagnosis of anorectal disorders, such as fecal incontinence and constipation.

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?



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August 25, 2026

Special 510(k) Summary

RE: Rapid Barostat Bag (RBB) Pump and Catheter System

Summary prepared by:

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Trade name: **Rapid Barostat Bag (RBB) Pump and Catheter System**

Common name: **Barostat pump and catheters**

Classification name: **Gastrointestinal motility system**

This Special 510(k) Summary is for the Rapid Barostat Bag Pump and Catheter System

Submission Number: **K262621**

Regulation Number: **21 CFR § 876.1725**

Regulation Name: **Gastrointestinal motility monitoring system.**

Product code: **FFX**

Device Class: **II**

Predicate Submission Number: **K160287**

Predicate Trade Name: **Rapid Barostat Bag (RBB) Pump and Catheter**

Indications for Use:

The Rapid Barostat Bag Pump and Catheter are used together for the inflation of a barostat balloon to measure rectal capacity, as well as rectal volume at points of sensation, urge, and discomfort, to determine hypersensitivity, hyposensitivity, or normal rectal sensations. These determinations aid in the diagnosis of anorectal disorders, such as fecal incontinence and constipation.

Device Description:

The Rapid Barostat Bag (RBB) Pump and Catheter System consists of a pump unit and a disposable catheter. The pump is made up of an air compressor pump, valves, pressure and flow sensors, and circuit boards, all contained within a flame retardant plastic enclosure with a touch-screen display. The pump unit is electrically powered by rechargeable batteries. The pump is wirelessly connected to a peripheral remote control for the patient to input different levels of sensation during the study. The catheter is made up of single-lumen PVC tubing with a plastic non-compliant barostat balloon at the distal end, and a female luer at the proximal end. The balloon end of the catheter is inserted into a patient's rectum, and the luer end is connected to the pump.



The study consists of two or more rounds of inflation and deflation of the catheter. The first round will inflate the balloon to the set internal pressure of 40 mmHg to determine the maximum volume of the rectum. The second round of inflation will be used to determine the volumetric points of sensation, urge, and discomfort associated with the patient's rectum. During the study, the pump will push air through the catheter tubing into the barostat balloon at a constant rate of 2mL/sec, while displaying the fluctuating pressure within the balloon onto the pump's touch screen display. When the patient begins to feel the sensation of the inflated balloon, they would push the "sensation" button on the remote control to transmit a signal to the pump. The inflation volume and pressure will be recorded at that point of reference. The pump will continue to inflate the balloon for the patient to report the point of the feeling of urge, and then discomfort, and the data points are collected and stored in the system's internal memory. Upon pressing the discomfort indicator button, the system will automatically stop the inflow of air into the balloon and begin to rapidly deflate the balloon at 3 mL/sec. By extrapolating the volume and pressure measurements recorded within the barostat balloon, the pump will be able to provide the healthcare professional with clearer data for a more accurate diagnosis of anorectal functions and rectum disorders.

1. Description of modification to RBB Pump:

In 2026, Mui Scientific launched a new model of the RBB pump with minor modifications. Several changes have been made to the previous model to improve the performance of our existing pump, including:

- Certain components were replaced to address minor issues caused by wear and tear.
- Some suppliers were replaced with components of the same specifications that are more efficient and present a lower risk.
- Minor design updates were implemented to the LCD panel, touch controller, and firmware to enhance performance and resolve wear-related issues.
- ESD improvements were made to the Charging Dock PCB to reduce risks and improve safety and ensure compliance with the updated requirements of IEC 60601.
- The user interface has been updated to improve usability and interaction with the device without altering the established test protocol.

Refer to *Table 1: Summary of RBB Pump Modification* between the two versions for more details. The details of these changes are outlined below:

Table 1: Summary of RBB Pump Modification

Area of Upgrade	Description of Change	Reason/Benefit of Change	Impact Assessment
LCD panel	LCD panel updated to an improved revision with enhanced optical performance and mechanical stability.	- Improves display clarity and long-term reliability - Reduces flickering and ghost-touches - Supports optically bonded touch panel computability - Lower display-related failures and returns - Previous LCD panel was discontinued.	- Supplier change - Modification does not affect the device's intended use, device performance, or device safety, display function remains unchanged. - Changes are limited to the display component only. - No modifications were made to the board hardware design. - Proves to be more efficient and presents a lower risk. No new risks have been introduced.



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			- Verification testing confirmed performance, safety, and reliability remain consistent with original hardware.
Touch panel	The touch panel has been upgraded with enhanced-thickness glass and OCA bonding for improved durability and clarity.	- Increased impact resistance and long-term assembly durability - Enhanced display readability, reduced glass breakage and internal reflections. - Improved perceived product quality.	- Supplier change - Modification does not affect the device's intended use, device performance, or device safety. - No new risks have been introduced. Existing risk controls remain effective. - Verification testing confirmed performance, safety, and reliability remain consistent with original hardware.
Touch Controller IC	Touch controller IC upgraded to a newer, more robust revision with improved noise immunity and stability.	- Enhanced Noise Immunity: Provides high immunity to inductive power noise, improving reliability. - Enhanced stable I²C communication, auto calibration support. - Improved touch stability, reduced false touches, improved ESD robustness.	- Supplier change - Modification does not affect the device's intended use, device performance, or device safety. - Functional behavior unchanged; improved robustness - Proves to be more efficient and presents a lower risk. No new risks have been introduced. - Verification testing confirmed performance, safety, and reliability remain consistent with original hardware.
ESD	Added TVS diode on DC input, ferrite bead on power line, and bonded DC barrel jack metal sleeve to system ground. All exposed metal contacts on the dock are now dielectric-coated.	- Improves ESD immunity based on EMC testing observations - Protects sensitive ICs from contact and air discharge events - Reduces transient overvoltage, noise, and latent failures - Improves grounding, power-line protection, and signal stability - Increases long-term reliability and robustness in high-static environments	- Modification does not affect the device's intended use, device performance, or device safety. - No change to electrical ratings or user interaction. - No new hazards; electrical overstress risk reduced. - Proves to be more efficient and presents a lower risk. No new risks have been introduced. - Verification testing confirmed performance, safety, and reliability remain consistent with original hardware.
Assembly Durability	Improved mechanical reinforcement, connector strain relief, and internal mounting stability.	- Improved mechanical strength and reliability. - Improve long-term durability and reduce wear-related failures.	- Modification does not affect the device's intended use, device performance, or device safety. - No new risks have been introduced. - Verification testing confirmed performance, safety, and reliability remain consistent with original hardware.



Firmware update	Firmware updated to improve boot stability, power handling, and system monitoring. Firmware structure refactored for reliability	- Improves startup reliability and eliminates intermittent boot failures and unexpected resets - Strengthens power-up sequencing and handling of slow or noisy peripherals - Improves battery efficiency, runtime, and reporting accuracy - Enhances sensor sampling, filtering, and low-flow measurement stability - Improves UI responsiveness and reduces operational latency - Supports future features, diagnostics, and easier firmware maintenance	- Modification does not affect the device's intended use, device performance, or device safety. - Firmware changes does not affect use of device by end user. - All functional tests confirm performance is consistent with prior specifications. - Improves essential performance - Software maintenance update only. - Proves to be more efficient and presents a lower risk. No new risks have been introduced. - Verification testing confirmed performance, safety, and reliability remain consistent with original hardware.
User Interface Software	Updated UI visuals and workflow layouts Faster UI transitions and reduced latency Improved status indicators and enhanced navigation.	- Improves usability and responsiveness, reducing user interaction errors - Reduces operational ambiguity and improves workflow efficiency - Enhances operator confidence during system operation	- Modification does not affect the device's intended use, device performance, or device safety. - Verification testing confirmed performance, safety, and reliability remain consistent with original hardware. - No change to use conditions. - No functional impact; cosmetic/usability only. - Use-related risks reduced. No new risks have been introduced.

NOTE: All modifications have been implemented to the RBB pump itself, and the updated pump continues to use the same catheter as the previous model. Therefore, there are no changes are made to the RBB catheter.

All of these changes have been validated and verified as outlined below:

- A comprehensive validation was conducted to assess and evaluate all implemented changes.
- Software validation was completed for the new software version to verify compatibility with the overall system.
- New electrical safety and EMC testing were performed. (Updated Electrical Safety testing report from Third party)
- An assessment was conducted of the Risk Management File to ensure that the risk profile had not changed.
- A new set of usability and human factors evaluations was conducted.
- A new set of Literature search and clinical Evaluation was conducted.
- A new set of post market assessment was conducted.

The changes are minor and were implemented to reduce risks and improve the device. They do not affect the device's intended use, fundamental technology, or performance specifications, and they do not introduce new risks or significantly modify existing risks. Comprehensive verification, validation, electrical safety/EMC, and usability testing confirmed that the device remains substantially equivalent to the previous version.



We have a robust work instruction in our QMS for managing substantial changes (201W1-Substantial Change). All relevant regulatory bodies were notified of the changes and asked to review the device modifications. After a detailed review of the changes in the second version, the modification was determined to be minor.

Refer to *Table 2: Parameter Comparison*, which presents a comparison between the two versions.

Table 2 Parameter Comparison

Parameter	Previous Model to New Model
Device Name / Model	Identical
Indications for Use	Identical
Target Population	Identical
Principle of Operation	Identical
Design (Geometry, Dimensions)	Identical
Materials (Patient-contacting)	Identical
Materials (Non-contacting)	Identical
Shelf Life	Identical
Packaging	Identical
Software	V1.3.121.85_260317
Firmware	V3.0.1_20260113
Accessories / Components	Identical
Usability / User Interface	Minor updates have been made to the user interface, but they were validated through extensive validation and usability testing.
Performance Specifications	Identical
Biocompatibility	Both of them uses the same catheter
Electrical Safety (if applicable)	Revised ESD (Electrostatic Discharge) to align with new IEC standards (IEC 60601-1-2, IEC 61000-4-2)
Mechanical Properties	Identical
Risk Profile	The risk management file has been updated for the new version of the device to include additional identified hazards. These risks have been evaluated and appropriately controlled in accordance with ISO 14971. The overall risk profile remains acceptable, and there is no change to the device classification.



Clinical Data	The Clinical Evaluation Report has been updated with additional details and requirements; however, no significant changes were made to the clinical data.
Labeling / IFU	Laser engraved label
Manufacturing Process	Improved mechanical reinforcement, connector strain relief, and internal mounting stability
Standards Compliance	Identical

2. Reason for changes in RBB pump:

The RBB pump was modified to improve reliability, performance, and regulatory compliance. Changes included replacing certain components and suppliers with equivalent alternatives to reduce risk and improve efficiency, implementing minor design updates to the LCD panel, touch controller, and firmware to address wear-related issues and enhance performance, and improving ESD protection on the Charging Dock PCB to increase safety and ensure compliance with the latest IEC 60601 requirements.

3. Substantial Equivalence Discussion

Following extensive verification testing, we conclude that the modified pump is substantially equivalent to the previously marketed version in terms of intended use, indications for use, and overall performance characteristics. The modifications were introduced to improve performance based on post-production feedback, particularly to address issues such as ghost touch and screen flickering. Additional design changes were also implemented to meet updated requirements in the latest revision of the electrical safety standards and to ensure compliance with the revised electrical safety testing requirements. These changes do not affect the device's intended use, fundamental performance or safety characteristics. We are claiming substantial equivalence between the modified version and its previously cleared model, referring to Table 5.

Table 3: Existing Model vs Modified Model

Product Name	510(k) Number	Version	Manufacturer
Rapid Barostat Bag Pump and its catheter	K160287	V1	Mui Scientific, Division of H & A Mui Enterprises Inc
Rapid Barostat Bag Pump and its catheter	Waiting for Special 510K clearance	V2	Mui Scientific, Division of H & A Mui Enterprises Inc

The modified version (V2) of the Rapid Barostat Bag Pump is similar to the previous model. Both versions have the same intended use, indications for use, intended patient population, contraindications, warnings, and other key characteristics. There are no modifications or changes to the RBB catheter, and both models use the same catheter.

4. Summary of non-clinical performance evaluations

Clinical testing is not required for this Special 510(k) because the modification does not change the device's intended use, fundamental scientific technology, or raise any new questions of safety or effectiveness. The change has been thoroughly evaluated through Mui Scientific's design control process, including risk analysis, design verification, and design



validation activities. In addition, numerous non-clinical performance tests have been conducted to assess the impact of the modification and to confirm that the device continues to meet all applicable performance, safety, and functional requirements. The testing demonstrated that the modified device performs as intended, remains substantially equivalent to the previously cleared device, and does not introduce any new hazards or increase existing risks. Based on the comprehensive non-clinical testing results and risk management evaluation, sufficient objective evidence exists to support the safety and effectiveness of the modified device without the need for clinical data.

Refer to Table 6 for a summary of the tests performed:

Table 4: Non-Clinical Bench Performance Testing

Evaluation Description	Summary
Usability Evaluation	Evaluation of the usability of the Modified device, it's IFU, and labels.
Electrical Safety Evaluation	Evaluation of the electrical safety testing of the device.
Software Evaluation including cybersecurity assessment	Evaluation of the software and its validation
Design Verification and Validation	Evaluation of the design of the device.

We have not made any changes to the materials or components that have direct or indirect patient contact; therefore, new biocompatibility testing is not required. The component changes were implemented to improve the long-term durability of the RBB pumps, which is expected to maintain or extend performance over time, not reduce it. As a result, there is no risk of decreased shelf life or service life, and additional shelf-life testing is not necessary. In addition, the packaging remains unchanged, so no further packaging validation or testing is required.

5. Conclusion

The modifications to the device do not introduce any significant changes to its intended use, indications for use, or fundamental performance characteristics. The information provided demonstrates that the modifications do not affect the device's intended use or overall safety and effectiveness.