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

March 14, 2017

Mui Scientific
Tammy Mui
Operations Manager
145 Traders Blvd. East, Unit #33-34
Mississauga, ON L4Z 3L3
Canada

Re: K160287
Trade/Device Name: Rapid Barostat Bag (RBB) Pump and Catheter
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: II
Product Code: FFX
Dated: January 23, 2017
Received: January 26, 2017

Dear Tammy Mui:

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 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" (21 CFR 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,

Joyce M. Whang -S

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160287

Device Name
Rapid Barostat Bag (RBB) Pump and Catheter

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Mui Scientific
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March 14, 2017

510(k) Summary

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

Summary prepared by:

Contact person:	**Tammy Mui**
Title:	**Operations manager**
Manufacturer:	**H&A Mui Enterprises, o/a Mui Scientific**
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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**
Regulation:	**21 CFR§ 876.1725**
Product Code:	**FFX**
510(k) submission #:	**K160287**

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

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 system consists of a pump unit and a disposable catheter. The pump uses an air compressor pneumatic system and is operated through a touch screen. It is electrically powered by rechargeable batteries and 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, also known as RBB Protocol, 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 2 mL/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 systems 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 disorder.

Predicate Device:

We are claiming equivalence to the following predicates:

Product Name	**510(k) Number**	**Manufacturer**
Distender Series II Barostat	K991288	G&J Electronics
Barostat Catheters	K973844	Mui Scientific

Substantial Equivalence for RBB Pump:

The Distender Series II Barostat machine is designed to perform a large range of isobaric and isochoric protocols along the gastrointestinal system, including the rectum. Common Barostat protocols, such as the Ascending Methods of Limit (AML) Tests and the Random Isobaric (RND) Tests, often require the Barostat to generate air at a high airflow rate (ex. generate 250 mL in 10 Seconds). Other protocols, such as the RBB Protocol, require the Barostat to generate air at low airflow rate (ex. 2 mL/sec). Users can manually fine-tune the Barostat's airflow rate from 2 mL/sec up to 25 mL/sec through the changing of the Barostat's Software and Hardware configuration.

Due to its freedom of configuration, the Barostat can be designed to perform a great variety of protocols, including the RBB Protocol. The RBB Protocol can be implemented into the Barostat through its Protocol Plus Deluxe software. A comparison test was performed to demonstrate that the RBB Pump can measure the same results as the Barostat when both machines are running the same RBB Protocol. Based on the test result, the RBB Pump is capable of measuring the same results as the barostat, concluding that the RBB Pump is substantially equivalent to the Distender Series II Barostat. Below, please find a comparison table of our RBB pump with the predicate:

	Submission Device	**Predicate Device**
Product Name	Rapid Barostat Bag Pump	Distender Series II Barostat
510(k) Holder	Submitter: Mui Scientific	G&J Electronics
510(k) Number	K160287	K991288
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.	The Barostat machine is a pneumatic device that indirectly measures the muscle tone of a hollow organ by inflating a barostat balloon and keeping the pressure constant while measuring the volume changes and rectal capacity
Energy Source	Rechargeable Batteries, AC Source	AC Source
Peripherals	Patient handheld device for recording points of sensation/urge/discomfort	Patient handheld device for recording points of sensation/urge/discomfort
Software	Integrated into pump unit, with touch screen monitor	Requires a separate standalone computer
Pressure Range	0 to 40 mmHg	0 to 60 mmHg
Airflow Rate	1.5 to 3 mL/sec	2 to 25 mL/sec
Performance	Obtained the same measurement for rectal capacity and compliance as the Predicate Device when running the same RBB Protocol	Obtained the same measurement for rectal capacity and compliance as the Submission Device when running the same RBB Protocol
Software Validation	Substantial equivalency demonstrated	Information not readily available by manufacturer.
Measurement Accuracy	Substantial equivalency demonstrated	Information not readily available by manufacturer.
Measurement Consistency	Substantial equivalency demonstrated	Information not readily available by manufacturer.

Substantial Equivalence for RBB Catheter:

The Rapid Barostat Bag Catheter is similar to barostat catheters currently manufactured by Mui Scientific in that they are made of the same tubing and balloon material, are assembled following similar procedures, and are also inflated with air for volume measurements of hollow organs within the gastrointestinal system.

The RBB Catheter is constructed with a single-lumen polyvinylchloride tubing, a 700 mL non-compliant polyolefin balloon at the distal end, and a polycarbonate luer at the proximal end (for connection to the RBB pump). The total catheter length is 100 cm, with the balloon length

being 10 cm. The balloon is secured with silk sutures and UV light cure glue. Inflation/deflation of the barostat balloon as well as pressure readings within the balloon are all conducted within the same single-lumen tubing.

The barostat catheters used with the Distender Series II Barostat machine are also manufactured by Mui Scientific (#K973844). These catheters are also made up of Polyvinylchloride tubing, with a non-compliant polyolefin balloon secured at the distal end. At the proximal end, instead of a polycarbonate luer, there is just a step up to a larger diameter polyvinylchloride tubing, approx. 6cm in length (for connection to a barb fitting on the Distender Series machine). Depending on the organ being measured, the barostat balloons can range in volume from 150mL – 1000mL. The length of the tubing can also vary, but standard is 100cm. These barostat catheters made specifically for the Distender Series II Barostat machine are also dual lumened, dedicating one lumen for balloon inflation/deflation only, and the second lumen for pressure measurement only.

Both RBB Catheter and barostat catheter have been tested to have a shelf life of two years and have passed the Cytotoxicity test, Irritation test, and Sensitization test for Biocompatibility. Below, please find a comparison table of our RBB Catheter with the predicate:

	Submission Device	**Predicate Device**
Product Name	RBB Catheter	Barostat Catheter
510(k) Holder	Submitter: Mui Scientific	G&J Electronics
510(k) Number	K160287	K973844
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.	The Barostat Catheter must be used in conjunction with a Barostat machine to indirectly measure the muscle tone of a hollow organ by inflating a barostat balloon and keeping the pressure constant while measuring the volume changes. Also measures rectal capacity.
Catheter OD	5.2 mm	Various
Lumen ID	3.2 mm	Various
Balloon Details	700 mL, 10 cm in length	Various volumes (150 mL – 1000 mL), various lengths
Material	Polyvinylchloride tubing, polyolefin balloon	Polyvinylchloride tubing, polyolefin balloon
Length	100 cm	Various (100 cm standard)
Connector End	Female luer	Polyvinylchloride tubing (10 cm length, OD 7.9 mm, ID 4.8 mm)
Number of uses	Single-use	Single-use and reusable models
Balloon Burst and Leak Tests	Substantial equivalency demonstrated	Substantial equivalency demonstrated

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Tensile Strength Test of Bonded/Glued Catheter Components	Substantial equivalency demonstrated	Substantial equivalency demonstrated
Biocompatibility	Passed Cytotoxicity, Irritation, and Sensitization tests	Passed Cytotoxicity, Irritation, and Sensitization tests
Shelf Life	2 years	2 years