February 12, 2025

GI Bionics, LLC
% Natalie Eagleburger
GI Bionics Regulatory Consultant
Cygnus Regulatory
6224 N 38th Street
Paradise Valley, Arizona 85253

Re: K242666
Trade/Device Name: Fecobionics Anorectal System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: KLA
Dated: January 11, 2025
Received: January 13, 2025

Dear Natalie Eagleburger:

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., 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

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)*

K242666

Device Name

Fecobionics Anorectal System

Indications for Use *(Describe)*

The Fecobionics Anorectal System is for use on patients requiring anorectal pressure studies and testing of defecatory function. The Fecobionics System must only be used by appropriately trained clinicians. The Fecobionics System enables evaluation of rectal sensitivity, rectal volume and shape, rectoanal inhibitory reflex, anal diameter during defecation, defecatory push pressure, and anorectal angle changes. The Fecobionics device is only intended to be used in adult patients.

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) SUMMARY

Fecobionics Anorectal System

I. SUBMITTER

GI Bionics, LLC
11107 Roselle Street, Suite 213
San Diego, CA 92121 USA

Phone: 858-249-7400
Contact Person: Natalie Eagleburger
Date Prepared: September 4, 2024

II. DEVICE

Trade Name:	Fecobionics Anorectal System
Common or Usual Name:	Anorectal Manometry System
Classification Name:	Gastrointestinal motility monitoring system
Regulatory Class:	Class II
Product Code and Regulation:	KLA, 21CFR 876.1725

III. PREDICATE DEVICE

Primary Predicate
THD AnoPress with THD SensyProbe Anorectal Manometry System (K180135)
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Fecobionics Anorectal System (Fecobionics System) is a portable anorectal manometry device for use on patients requiring anorectal pressure studies and evaluation of defecatory function. The Fecobionics System consists of three main components:

- AR-100 Probe,
- DH-100 Data Hub, and
- Fecotracker App (installed on a provided PC-based laptop).

The AR-100 Probe is a single-use, non-sterile disposable, battery-powered probe designed to be inserted manually into the rectum and wirelessly transmit data to the external Data Hub, which wirelessly sends the data to the PC with the Fecotracker App. The system provides clinicians with real-time manometric data and geometric mapping information in a single examination. The probe features a balloon designed to be filled with saline by means of a detachable fill tube and a Luer-Lock connection with a syringe. The inflation of the balloon allows the evaluation of sensation thresholds of the lower rectum and assesses and triggers Recto Anal Inhibitory Reflex (RAIR). To mimic the defecation process, the wireless probe is designed to be defecated as an untethered free distensible mass. In total, the Fecobionics System enables the evaluation of rectal sensitivity, rectal volume, and shape, recto anal inhibitory reflex, anal diameter during defecation, defecatory push pressure, and anorectal angle changes.

The AR-100 Probe is 10cm long, and its interior bendable core is 10mm in diameter. When inflated with the allowed maximum saline inflation volume (100 mL), the balloon reaches a diameter of up to 5cm.

V. INDICATIONS FOR USE

The Fecobionics Anorectal System is for use on patients requiring anorectal pressure studies and testing of defecatory function. The Fecobionics System must only be used by appropriately trained clinicians. The Fecobionics System enables evaluation of rectal sensitivity, rectal volume and shape, recto anal inhibitory reflex, anal diameter during defecation, defecatory push pressure, and anorectal angle changes. The Fecobionics device is only intended to be used in adult patients.

A comparison of the intended use of the proposed device and the predicate device is provided in the table below:

Characteristic	Subject Device Fecobionics Anorectal System	Predicate Device THD AnoPress with THD SensyProbe Anorectal Manometry System (K180135)	Equivalence Comparison
Indications for Use	The Fecobionics Anorectal System is for use on patients requiring anorectal pressure studies and testing of defecatory function. The Fecobionics System must only be used by appropriately trained clinicians. The Fecobionics System enables evaluation of rectal sensitivity, rectal volume and shape, rectoanal inhibitory reflex, anal diameter during defecation, defecatory push pressure, and anorectal angle changes. The Fecobionics device is only intended to be used in adult patients.	The THD Anopress device must be used exclusively to assess the average sphincter tone due to the pressure exerted by the muscles in the anal canal on the specially design THD Probes. THD Anopress must only be used by appropriately trained medical staff. Furthermore, the THD SensyProbe enables evaluation of rectal sensitivity and capacity and the anorectal inhibitory reflex through connection to a syringe and filling of the balloon on the probe with air. The THD Anopress with THD SensyProbe is intended to be used in adults only.	Equivalent

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Fecobionics Anorectal System and predicate THD Anopress with THD SensyProbe are identical in that both are portable anorectal manometry devices for anorectal pressure studies and evaluation of defecatory function. Both devices utilize probes inserted into the rectum that measure anal pressures and wirelessly transmit that data from the probe to a main unit to the computer. The probes both feature balloons or bags designed to be filled, allowing additional measurements. The Fecobionics Anorectal System has design and technological characteristics similar to the predicate THD Anopress with THD SensyProbe, including similar principles of operation and energy sources. Minor differences in technological characteristics do not raise new questions of safety and efficacy when all listed warnings and cautions are followed.

The key technological differences center around the Fecobionics probe being designed to more closely imitate the defecation process compared to the predicate and provide real-time geometric mapping and manometric profile data. Specific technological differences are as follows:

- The Fecobionics probe is bendable, utilizes several different patient-contacting materials, and contains multiple pressure sensors as opposed to the stiff predicate device. The Fecobionics probe has additional measurement capabilities to allow provision of real-time geometric mapping and manometric profile data to clinicians in a single examination,
- The measurement bladder configuration differs in that the Fecobionics probe is surrounded by a single bag which is filled with saline instead of the multiple air-filled balloons of the predicate device, and
- The Fecobionics probe may be detached from the fill tube following fill.

The results from preclinical and clinical evaluations demonstrate that the Fecobionics Anorectal System's technological and performance characteristics meet defined design requirements and can safely perform anorectal manometry in a manner equivalent to the predicate for its intended use. Performance data demonstrate that the Fecobionics Anorectal System performs as intended and is substantially equivalent to its predicate.

A comparison of the technological characteristics of the subject device and the predicate device is provided in the table below:

Characteristic	Subject Device Fecobionics Anorectal System	Predicate Device THD Anopress with THD SensyProbe Anorectal Manometry System (K180135)	Equivalence Comparison
Trade Name	Fecobionics Anorectal System	THD Anopress with THD SensyProbe Anorectal Manometry System	N/A
Product Code	KLA	KLA	Same
Regulation Number	21 CFR 876.1725	21 CFR 876.1725	Same
Regulatory Class	II	II	Same
Use	Rectal Device Single Use Probe Reusable data hub / console	Rectal Device Single Use Probe Reusable main unit / console	Same
Target Population	Adult Population	Adult Population	Same
Anatomical Sites	Rectum	Rectum	Same
Where Used	Clinical Diagnostic Room or Labs	Clinical Diagnostic Room or Labs	Same
Energy Used	Battery powered for inserted device and wireless transmission unit. 120V 60 Hz (USA) for the tablet PC with display.	Battery powered for inserted device and 120V 60 Hz (USA) for the PC with display.	Same
Composition	Manometry system includes: **(1) Probe** Fecobionics Probe features a bendable core with embedded sensors and batteries inside a bag (membrane) that may be inflated for rectal distension. The volume and shape of the bag is related to rectal size, rectal sensitivity, and the passage through the anal canal during defecation. The motion processor units (MPUs) measure orientation of the device at the front and rear and a bending angle reflecting the anorectal angle can be computed pressure measures contractile capability and anal sphincter relaxation. The bag is manually inflated by the clinician with saline. **(2) Main Unit** Main unit (data hub) processes manometry data from the probe and send it wirelessly (Wi-Fi) to Fecotracker app **(3) App** Provides data to users who are medically trained in these procedures and familiar with a variety of parametric data.	Manometry system includes: **(1) Probe** THD Anopress catheter has two probe options as follows: ○ one sensitive balloon (membrane) located on the introducer (THD PressProbe). ○ with one sensitive balloon (membrane) located on the introducer and one larger balloon located in the most distal end (THD SensyProbe). Membrane is related to manometry test; the larger balloon is related to rectal sensation test. The balloon is inflated with air by the main unit for the manometry test and manually inflated by the clinician with air for the sensation test. **(2) Main Unit** Main unit (console) processes manometry data from the probe and send it wirelessly (Bluetooth) to THD app **(3) App** Provides data to users who are medically trained in these procedures and familiar with a variety of parametric data.	Similar / Equivalent
Mechanism of Action	Saline filled bag surrounding probe measures pressure, contractile force, anal sphincter tone, anal relaxation, RAIR. Bag allows measurement of rectal size and sensitivity and diameter during anal canal passage. Pressures that measures MPUs that measure orientation and anorectal angle	Air-filled balloon on probe for: measuring anal pressure for manometry test, by the means of a membrane on the probe (all THD Probes) and evaluation of RAIR and rectal sensation, by the mean of a distal end sensation balloon (only THD SensyProbe)	Equivalent

Characteristic	Subject Device Fecobionics Anorectal System	Predicate Device THD Anopress with THD SensyProbe Anorectal Manometry System (K180135)	Equivalence Comparison
Detected Parameters	Resting rectal Pressure Contractile pressure during defecation Anal Squeeze Pressure Anal relaxation Front-rear pressure difference Straining pressure and angle Real Time Pressure Measurement Anal Contractile Reflex Cough Reflex Rectal Sensation Thresholds Bag volume and shape RAIR	Resting Pressure Squeeze Pressure Endurance Strain Pressure Squeeze/Rest Rate Real Time Pressure Measurement Anal Contractile Reflex Cough Reflex Rectal Sensation Thresholds RAIR	Equivalent
Component in contact with patient	Disposable probe (including bag) and fill tubing	Disposable Catheter/probe (including membrane and distal end balloon), inflation/fill tubing and connections and cables	Equivalent
Inserted Component Dimensions	The Fecobionics Device core is 10cm long and 10mm in diameter and is bendable. The surrounding bag is approximately 9 cm long and can be filled with saline up to 100ml and a diameter of up to 5cm. Pressures can be measured reliably up to 250mmHg	THD PressProbe membrane has a diameter varying from 14.4 mm (empty membrane) to 16.6 mm (membrane inflated to 150 mmHg), The THD PressProbe is inserted in the anal canal and inflated to up to 150 mmHg, so that the sphincter exerts a compression on the membrane until 390 mmHg. THD SensyProbe membrane has the same diameter and performances as the THD PressProbe. The additional balloon positioned on the top of the introducer reaches a diameter of 70 mm when inflated with 200 ml of air. The allowed maximum inflation volume for distal end balloon is 180 ml of air.	Similar / Equivalent
Pressure Data Transmission	Wireless, real-time (RF) to main unit Wireless, real-time (Wi-Fi) from main unit to app	Wired, real-time to main unit Wireless, real-time (Bluetooth) from main unit to app	Similar / Equivalent
Performance	Bench, clinical, and comparative testing	Bench and Comparative Testing	Similar/ Equivalent
Patient Contacting Materials	Silicone (bag, outer surface of probe) Polyurethane and polyamide 12 (fill tube) 2-0 suture, ultra-high molecular weight polyethylene (UHMWPE) (tether)	Poly-urethane (membrane) C-Flex (SEBS – Styrene-ethylene-butadiene-styrene block polymer) (distal end balloon)	Similar/ Equivalent
Contact Type	Surface Contacting (Mucosal Membranes, limited duration <24 hrs) ISO 10993-1	Surface Contacting (Mucousal Membranes, limited duration <24 hrs) ISO 10993-1	Same
Sterilization	Non-Sterile	Non-Sterile	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Preclinical and clinical tests were conducted on the Fecobionics Anorectal System to demonstrate that it meets defined design requirements and can perform in a manner equivalent to devices currently on the market used for its intended use. Testing included verification and validation bench testing, electrical safety and EMC evaluations, software verification and validation, and clinical testing. The design, testing, and technical information provided for the Fecobionics Anorectal System also comply with relevant recognized consensus standards where applicable and as defined in the table below. The table below summarizes the performance testing conducted.

Test	Reference Standards OR Test Method Summary	Results and Conclusions
Biocompatibility	• ISO 10993-1 • ISO 10993-5 • ISO 10993-10 • ISO 10993-11 • ISO 10993-23	All results met acceptance criteria and demonstrate the Fecobionics Anorectal System is non-cytotoxic, a non-sensitizer, a non-irritant, non-pyrogenic, is suitable for its intended use, and is substantially equivalent to the predicate device.
Electrical Safety	• IEC 60601-1	All results met acceptance criteria and demonstrate the Fecobionics Anorectal System is substantially equivalent to the predicate device.
Electromagnetic Compatibility (EMC)	• IEC 60601-1-2	All results met acceptance criteria and demonstrate the Fecobionics Anorectal System is substantially equivalent to the predicate device.
Software Verification and Validation	• IEC 62304	All results met acceptance criteria and demonstrate the Fecobionics Anorectal System is substantially equivalent to the predicate device.
Functional Performance accuracy verification in simulated use conditions (new and aged devices, as appropriate)	Verification of functional performance and accuracy of the Fecobionics Anorectal System for measured parameters.	No difference in results between aged and not aged samples. When applicable, the relevant performances and accuracy obtained are comparable with the predicate device. All results met acceptance criteria and demonstrate the Fecobionics Anorectal System is suitable for its intended use and is substantially equivalent to the predicate device.
Mechanical and Performance Tests (new and aged devices, as appropriate)	Mechanical • Verification of probe geometric specifications (length and diameter) • Probe bending force • Verification of bag expanded diameter • Bag peel force strength, burst volume • Holding force of tether anchoring system • Absence of sharp features • Fill tube dimensions (outer diameter and length) and removal force • Tensile testing of the joints and bonded components of the fill tube • Device seal performance • Ingress protection Performance • System wireless transmission distance • Cross-sectional area electrical field	No difference in results between aged and not aged samples. When applicable, the relevant performances are comparable with the predicate device. All results met acceptance criteria and demonstrate the Fecobionics Anorectal System is suitable for its intended use and is substantially equivalent to the predicate device.

Test	Reference Standards OR Test Method Summary	Results and Conclusions
	frequency • Probe battery life • Data Hub battery life • Data Hub console cleaning	
Fecobionics Anorectal System Clinical Study	A nonsignificant risk (NSR), observational, randomized clinical study was conducted to evaluate the sensory aspect of the Fecobionics Anorectal System in comparison to the predicate during fecal manometry studies.	The outcomes on 10 patients met the criteria for success related to the sensory measurements as outlined in the protocol. A high correlation was found between the sensation levels and the volume data with the two technologies. No questions of safety were raised by the study. The results demonstrate the Fecobionics Anorectal System is suitable for its intended use and is substantially equivalent to the predicate device.

Manufacturing and traceability of devices tested were conducted in accordance with 21 CFR Part 820 Good Manufacturing Practices. In all instances, the Fecobionics Anorectal System functioned as intended and the results observed were as expected. These test results confirm that Fecobionics Anorectal System complies with the recognized standards, meets the design specifications and performance requirements for the intended use, and is substantially equivalent to the predicate.

VIII. CONCLUSIONS

The Fecobionics Anorectal System is substantially equivalent to the THD AnoPress with THD SensyProbe Anorectal Manometry System predicate device (K180135). The Fecobionics Anorectal System and its predicate share the same Product Code and classification as a Gastrointestinal motility monitoring system. The Fecobionics Anorectal System has an equivalent intended use as the predicate device and the same indications for use. The Fecobionics Anorectal System also has a similar design and technological characteristics as the predicate device. Minor differences in design and technological characteristics do not raise different questions of safety and efficacy when all listed warnings and cautions are followed.

The results from preclinical and clinical evaluations demonstrate that the technological and performance characteristics of the Fecobionics Anorectal System meet defined design requirements. Performance and clinical data demonstrate that the Fecobionics Anorectal System performs as intended and is substantially equivalent to its predicate. This conclusion is based upon equivalence in the device's (1) design, (2) material technological characteristics, (3) technological characteristics, (4) principles of operation, (5) and intended use.