May 21, 2025

AnX Robotica Corporation
Tim Thomas
VP, Regulatory/Quality/Clinical
6010 W Spring Creek Parkway
Plano, Texas 75024

Re: K250493
Trade/Device Name: MotiliCap GI Monitoring System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: NYV
Dated: February 18, 2025
Received: February 20, 2025

Dear Tim Thomas:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
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. | K250493 |

Please provide the device trade name(s).

MotiliCap GI Monitoring System

Please provide your Indications for Use below.

The MotiliCap GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.
Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.
Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.
The system measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.
Not for use in pediatric patients.

Please select the types of uses (select one or both, as applicable).

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

# 510(K) SUMMARY

MotiliCap GI Monitoring System

**510(k) Number K250493**

## 1. SUBMITTER

**Applicant's Name:**
AnX Robotica, Corp.
6010 W. Spring Creek Parkway
Plano, TX 75024
Phone: (469) 606-9495

**Primary Contact:**
Tim Thomas, RAC
VP, Regulatory/Quality/Clinical
Phone: (770) 480-2911
Email: tim.thomas@anxrobotics.com

## 2. DATE PREPARED

February 18, 2025

## 3. DEVICE

**Trade Name:** MotiliCap GI Monitoring System

**Classification Code:**
**Name:** Gastrointestinal motility monitoring system
**Product Code:** NYV
**Regulation No:** 876.1725
**Class:** II
**Classification Panel:** Gastroenterology/Urology

## 4. PREDICATE DEVICES

**Primary** – SmartPill GI Monitoring System (K092342).

## 5. DEVICE DESCRIPTION

The MotiliCap GI Monitoring System is comprised of the following components:

- MotiliCap Capsule (Catalog Number: CP-US-7010)
- Data Recorder (Catalog Number: MO-US-8001)
- Computer Software (MotiliScan: V1. MO-US-8005)
- Smartphone App (MotiliCap: V1. MO-US-8006)

The single-use capsule consists of the pressure sensor, the pH sensor, and the temperature sensor, which separately measure the pressure, pH, and temperature in the GI tract to determine transit times of the stomach, small bowel, and colon. The system provides information that aids clinicians in the evaluation of motility-related disorders. The data

recorder records biomedical data transmitted by the capsule. The MotiliScan software is installed on a general-purpose computer. Before the examination, the software can create a case to start a test. After the test is complete, the software can receive, and process downloaded test data from the data recorder and graphically display the data for easy analysis and review. The MotiliScan software analyzes data and calculates motility indices such as GET, SBTT, CTT, and WGTT. The MotiliCap App is installed on a smartphone. This App is connected to the data recorder via Bluetooth, displays the connection status, and shows information about the capsule connected to the data recorder.

## 6. INDICATIONS FOR USE

The MotiliCap GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.

Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.

Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.

The system measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.

Not for use in pediatric patients.

## 7. SUBSTANTIAL EQUIVALENCE

**Indications**

The proposed indications for use of the MotiliCap GI Monitoring System are:

*The MotiliCap GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.*

*Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.*

*Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.*

*The system measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.*

*Not for use in pediatric patients.*

The current indications for use of the SmartPill GI Monitoring System (K092342) are as follows:

*The SmartPill GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.*

*Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.*

*Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.*

*The system measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.*

*Not for use in pediatric patients.*

The indications for use of the MotiliCap GI Monitoring System are the same to the indications for use of the FDA clearance for the SmartPill GI Monitoring System (K092342).

**Technological Characteristics**

The technological characteristics of the MotiliCap GI Monitoring System are like the SmartPill GI Monitoring System. Each system consists of a single-use capsule which contains a pressure sensor, the pH sensor, and the temperature sensor, which separately measure the pressure, pH, and temperature in the GI tract to determine transit times of the stomach, small bowel, and colon. Each system consists of a data recorder to capture the data from the capsule and software provides information that aids clinicians in the evaluation of motility-related disorders. The MotiliCap GI Monitoring System utilizes a smart phone app vs the data recorder to capture events from the patient.

The technological characteristics of the MotiliCap GI Monitoring System are the same to the technological characteristics of the SmartPill GI Monitoring System (K092342).

## 8. PERFORMANCE DATA

**Clinical Experience**

Evaluation of substantial equivalence to the predicate device was based largely on the technological similarities of the devices and the results of the bench testing, as detailed

below. A small clinical evaluation of the device supported that the device could function as intended in the clinical environment and the patient is generally satisfied with the examination and software operation.

**Bench Testing**

The MotiliCap GI Monitoring System demonstrates the ability to measure pressure, pH, and temperature per the developed specifications. The MotiliCap GI Monitoring System demonstrates compliance to the general requirements for medical devices and the applicable capsule endoscopy special control requirements including, battery life test, battery safety test, pH accuracy test, temperature accuracy test, pressure accuracy test, FCC data transmission verification, , bite test, pH resistance test, bioburden test, biocompatibility tests, EMC testing, transit simulation tests, and shelf-life test.

## 9. CONCLUSION

The indications for use for the MotiliCap GI Monitoring System and the SmartPill GI Monitoring System are the same. The technological characteristics of the two capsules are the same. Therefore, the MotiliCap GI Monitoring System is substantially equivalent to the SmartPill GI Monitoring System.