June 26, 2025

Atmo Biosciences Ltd
Ian Macfarlane
Regulatory Manager
436 Elgar Rd
Box Hill, VIC 3128
Australia

Re: K250940
Trade/Device Name: Atmo Gas Capsule System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: NYV
Dated: March 28, 2025
Received: March 28, 2025

Dear Ian Macfarlane:

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

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.

510(k) Number *(if known)*
K250940

Device Name
Atmo Gas Capsule System

Indications for Use *(Describe)*
The Atmo® Gas Capsule System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal transit times are used for evaluating motility disorders.

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, to aid in differentiating slow and normal transit constipation. In the case where ileocecal junction transit cannot be determined, the system will report combined Small and Large Bowel Transit Time (SLBTT).

Transit times are derived from measures of temperature, hydrogen concentration, and carbon dioxide concentration, and indicators of oxygen level, Capsule tumble, and antenna reflectance.

Not for use in pediatric 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.

510(k) SUMMARY - Atmo Gas Capsule System

1 Submitter and Device Details

Date Prepared:	19-June-2025
Manufacturer:	Atmo Biosciences Ltd 436 Elgar Rd Box Hill, VIC 3128 Australia
Contact Information:	Phone: +61 3 9945 7510 Cell: +61 400 807 893 Email: ian.macfarlane@atmobiosciences.com
Contact Person:	Ian Macfarlane Regulatory Manager
Device Trade Name:	Atmo® Gas Capsule System
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1725 Gastrointestinal motility monitoring system
Product Code:	NYV Capsule Gastrointestinal Motility System
Predicate Device(s)	SmartPill GI Monitoring System, version 2.0
Predicate Device 510(k) number	K092342

2 Device Description

The Atmo Gas Capsule System is a prescription only ingestible telemetric medical device system used to measure transit times of the gastrointestinal (GI) tract. The system consists of a single-use Capsule, re-usable Receiver, Mobile Device with Clinician App, and an online Clinician Portal.

Sensors onboard the Capsule provide measurements for temperature, hydrogen concentration, and carbon dioxide concentration, along with indicators of oxygen level, capsule tumble, and antenna reflectance that are used to identify regional gastrointestinal anatomical landmarks. The Capsule data is transmitted from within the GI tract via radiofrequency communication to a Receiver worn by the patient. The Mobile Device runs the Atmo Clinic App, a software application which guides the clinician through the pairing process, Capsule administration, and subsequent transfer of stored data from the Receiver to a cloud server. The Atmo Clinician Portal, accessible through a web browser, displays the resulting data and provides guidance for the physician to review, confirm and create a downloadable Motility Study Report containing whole and regional gut transit times.

3 Indications for Use

The Atmo Gas Capsule 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 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, to aid in differentiating slow and normal transit constipation. In the case where ileocecal junction transit cannot be determined, the system will report combined Small and Large Bowel Transit Time (SLBTT).

Transit times are derived from measures of temperature, hydrogen concentration, and carbon dioxide concentration, and indicators of oxygen level, Capsule tumble, and antenna reflectance.

Not for use in pediatric patients.

4 Summary of Technological Characteristics

The Atmo Gas Capsule System has similar key physical attributes to the Predicate. The Atmo Capsule and Receiver are slightly smaller and the overall usability reflects current human factors engineering best practice. The Atmo Gas Capsule System incorporates different sensors and employs a different algorithm to make its determination of gastrointestinal tract transit times.

Data flow for the Atmo system is from the Capsule to the Receiver, then via the cloud to an online portal for analysis, viewing and interpretation by the clinician. The Predicate transmits data from the capsule to a receiver, then to a local PC for analysis, viewing and interpretation by the clinician.

A comparison of the Atmo Gas Capsule and Predicate device attributes is shown below.

Device / Characteristic	**Atmo Gas Capsule System**	**SmartPill GI Monitoring System, Version 2.0 (Predicate Device, K092342)**
Capsule		
Sensors	• Temperature and Relative Humidity Sensor • Thermal Conductivity Detector (TCD) • Volatile Organic Compound (VOC) Sensor • Triaxial Accelerometer • Antenna Reflectometer	• Temperature Sensor • pH Sensor • Pressure Sensor
Transmission Signal to Receiver	RF Signal centered frequency of 433.9 MHz (radiating between 433.5-434.5 MHz)	RF Signal centered frequency of 434.2 MHz (radiating between 426-445 MHz)[1]
Data Stream	Continuous	Continuous
Energy used	Silver oxide batteries	Silver oxide Batteries
Battery Life	>240 hrs. (4 days gas sensing, then a further 6 days of temperature only sensing)	>120 hrs
Size	27.8 mm (length) 11.1 mm (diameter)	< 35 mm (length) < 15 mm (diameter)
Weight	3.8 g	4.5 g[1]

Device / Characteristic	Atmo Gas Capsule System	SmartPill GI Monitoring System, Version 2.0 (Predicate Device, K092342)
Sterility	Non-sterile	Non-Sterile
Reuse	Single Use	Single Use[1]
User Performed Calibration	No user calibration is required. Capsule calibration is performed as part of the manufacturing process.	pH sensor calibration is performed by the user at time of administration.
Receiver		
Receiver	Rechargeable, belt worn Receiver	Rechargeable, belt clip or lanyard worn receiver
Data Communication from Receiver	USB cable transfers data from the Receiver to the Mobile Device which uploads the data to the cloud server for analysis	Docking station and USB
Analysis Software		
Identification of Transit Markers	Software automatically identifies capsule ingestion, gastric emptying through gastroduodenal junction (GDJ), ileocecal junction (ICJ), and body exit. The user must manually confirm each marker.	Software automatically identifies capsule ingestion, gastric emptying (GDJ), ileocecal junction (ICJ), and body exit. The user must manually confirm each marker.
GI Regional Transit Measurements	• GET – Gastric emptying time • SBTT – Small bowel transit time • OCTT – Orocecal transit time • SLBTT – Combined small and large bowel transit time • CTT – Colonic transit time • WGTT – Whole gut transit time	• GET – Gastric emptying (transit) time • SBTT – Small bowel transit time • SLBTT – Combined small and large bowel transit time • CTT – Colonic transit time • WGTT – Whole gut transit time
Recording Events	Bowel movements recorded via single button press on the receiver. Additional information such as meals and symptoms can be recorded in a provided patient diary.	Any event's timing recorded via single button press on the receiver. Event details are recorded in the patient diary (e.g., meals, bowel movement, gas, drank liquid, and went to bed)
Platform	Clinician portal hosted on a secure cloud server accessed using an internet connected computer	Software on a computer

[1] SmartPill® GI Monitoring System, User Manual, MotiliGI® v3.0, March 2013

5 Performance Data

5.1 Non-clinical Testing

Non-clinical testing was performed to verify device specifications and confirm the safety and performance of the device. In all instances, the Atmo Gas Capsule System functioned as intended. Non-clinical testing included:

- Biocompatibility
- Human factors
- Electrical safety
- Electromagnetic compatibility
- Software, including cybersecurity

- Systems and Mechanical
- Cleaning and disinfection of reusable components
- Packaging
- Shelf-life

5.2 Clinical Testing

A multi-site, prospective study was conducted across 12 US sites and 1 OUS site, where a total of 213 participants with confirmed or suspected dysmotility issues of the gastric and/or colonic regions were recruited. The primary objective of this study was the assessment of the agreement of the Atmo Gas Capsule System and the Predicate measurements with regard to both GET and CTT. All participants were asked to ingest both the Atmo Gas Capsule System and the Predicate device concurrently. Bland-Altman analysis showed agreement between Atmo Gas Capsule System and the Predicate device for GET and CTT, with all pre-determined end points successfully met.

No serious adverse events (SAE) were associated with the Atmo Gas Capsule system. No device deficiencies led to SAEs or serious adverse device effects. Minimal adverse events (AE) were observed with all reported AEs being expected and common to the study population.

Based on the clinical performance as documented in the pivotal clinical study, the Atmo Gas Capsule System has a safety and effectiveness profile that is similar to the Predicate Device.

6 Substantial Equivalence

The Atmo Gas Capsule System is substantially equivalent to the SmartPill GI Monitoring System, version 2.0. The Atmo Gas Capsule System has the same intended uses and substantially similar indications, technological characteristics, and principles of operation as the Predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labelled. In addition, the minor technological differences between the Atmo Gas Capsule System and the Predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Atmo Gas Capsule System is as safe and effective as the SmartPill GI Monitoring System, version 2.0. Thus, the Atmo Gas Capsule System is substantially equivalent.