May 22, 2026

Atmo Biosciences Ltd
Allison Lockwood
Head of Quality and Regulatory
436 Elgar Rd
Box Hill, VIC 3128
Australia

Re: K253569
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: April 22, 2026
Received: April 22, 2026

Dear Allison Lockwood:

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 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,

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)*
K253569

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, carbon dioxide concentration, and contractility frequency, and indicators of oxygen level, Capsule tumble, and antenna reflectance.

The device displays a contractility frequency map based on measurements of capsule movement caused by gastrointestinal pressures and contractions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY - Atmo Gas Capsule System

1 Submitter and Device Details

Date Prepared:	08-MAY-2026
Manufacturer:	Atmo Biosciences Ltd 436 Elgar Rd Box Hill, VIC 3128 Australia
Contact Information:	Phone: +61 3 9945 7510 Cell: +61 403 000 655 Email: allison.lockwood@atmobiosciences.com
Contact Person:	Allison Lockwood Head of Quality and Regulatory
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)	Atmo Gas Capsule System (K250940)
Predicate Device 510(k) number	K250940

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, carbon dioxide concentration and contractility frequency, 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 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, carbon dioxide concentration, and contractility frequency, and indicators of oxygen level, Capsule tumble, and antenna reflectance.

The device displays a contractility frequency map based on measurements of capsule movement caused by gastrointestinal pressures and contractions.

Not for use in pediatric patients.

4 Summary of Technological Characteristics

The Atmo Gas Capsule System has similar key physical attributes to the Predicate Atmo Gas Capsule System which was cleared in submission K250940. The Proposed Atmo Gas Capsule System and its Predicate utilize the exact same hardware and the proposed change is entirely cloud software related. The Proposed Atmo Gas Capsule System employs the same algorithm to make its determination of gastrointestinal tract transit times as the Predicate device. The only difference is the addition of Contractility Frequency as a supplemental secondary trace to be utilized by the clinician in the study review process.

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

Device **Characteristic**	**Atmo Gas Capsule System ("Proposed Device")**	**Atmo Gas Capsule System (Predicate Device, K250940)**
Sensors	• Temperature and Relative Humidity Sensor • Thermal Conductivity Detector (TCD) • Volatile Organic Compound (VOC) Sensor • Triaxial Accelerometer • Antenna Reflectometer	• Temperature and Relative Humidity Sensor • Thermal Conductivity Detector (TCD) • Volatile Organic Compound (VOC) Sensor • Triaxial Accelerometer • Antenna Reflectometer
Transmission Signal to Receiver	RF Signal centered frequency of 433.9 MHz (radiating between 433.5-434.5 MHz)	RF Signal centered frequency of 433.9 MHz (radiating between 433.5-434.5 MHz)
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)	>240 hrs. (4 days gas sensing, then a further 6 days of temperature only sensing)
Size	27.8 mm (length) 11.1 mm (diameter)	27.8 mm (length) 11.1 mm (diameter)
Weight	3.8 g	3.8 g
Sterility	Non-sterile	Non-Sterile
Reuse	Single Use	Single Use
User Performed Calibration	No user calibration is required. Capsule calibration is performed as part of the manufacturing process.	No user calibration is required. Capsule calibration is performed as part of the manufacturing process.
Receiver	Rechargeable, belt worn Receiver	Rechargeable, belt 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	USB cable transfers data from the Receiver to the Mobile Device which uploads the data to the cloud server for analysis
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 through gastroduodenal junction (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 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
Displayed Traces	• Carbon Dioxide • Oxygen Level • Temperature • Hydrogen • Capsule Tumble • Antenna Reflectance • Contractility Frequency	• Carbon Dioxide • Oxygen Level • Temperature • Hydrogen • Capsule Tumble • Antenna Reflectance
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.	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.
Platform	Clinician portal hosted on a secure cloud server accessed using an internet connected computer	Clinician portal hosted on a secure cloud server accessed using an internet connected computer
Shelf life	Capsule 12 months	Capsule 12 months

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 (as per K250940)
- Human factors (Report on addition of Contractility Frequency)
- Electrical safety (as per K250940)
- Electromagnetic compatibility (as per K250940)
- Software, including cybersecurity
- Systems and Mechanical
- Cleaning and disinfection of reusable components (as per K250940)
- Packaging (as per K250940)
- Shelf-life

5.2 Clinical Testing

In order to demonstrate that the addition of the Contractility Frequency Map to the Atmo Gas Capsule System does not reduce the clinical effectiveness of the device, previously collected study data from the Atmo Capsule were reinterpreted by two new Central Readers with this feature available and compared against the reference standard (SmartPill GI Monitoring System). The comparison of the Atmo Capsule with and without the Contractility Frequency Map is similar when comparing it to the reference standard via Bland-Altman analyses. 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. Collectively, these findings demonstrate that there is no evidence to indicate that the addition of the Contractility Frequency Map feature reduces clinical effectiveness of the Atmo Capsule.

6 Substantial Equivalence

The Atmo Gas Capsule's Indications for Use statement includes both the clinical application and the system's general purpose and functions (Intended Use).
The Proposed Indications for Use do not change the clinical application of the system but rather adds Contractility Frequency as a new function to aid the clinician with the evaluation of the clinical application.
To incorporate this new function, the Indications for Use for the device have two additions to that of the Predicate device. These are:

1. The inclusion of contractility frequency in transit time derivation.
2. The inclusion of the statement:
   " The device displays a contractility frequency map based on measurements of capsule movement caused by gastrointestinal pressures and contractions."

These additions do not constitute a new clinical application as the contractility frequency provides the clinician with an additional secondary indicator to support transit marker placement. Performance data demonstrate that the Atmo Gas Capsule System is as safe and effective as the predicate. Thus, the Atmo Gas Capsule System is substantially equivalent.