



November 26, 2025

MGC Diagnostics Corporation
% Amy Fowler
Regulatory Counsel
Pathmaker FDA Law PLLC
1450 Lilac Dr. N
Suite 270
Minneapolis, Minnesota 55422

Re: K251674

Trade/Device Name: Fenom Flo™ FeNO Monitoring System
Regulation Number: 21 CFR 862.3080
Regulation Name: Breath nitric oxide test system
Regulatory Class: Class II
Product Code: MXA
Dated: May 19, 2025
Received: October 14, 2025

Dear Amy Fowler:

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 and Part 809); 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,

JOSEPH A. KOTAREK -S
Digitally signed by
JOSEPH A. KOTAREK -S
Date: 2025.11.26
12:42:41 -05'00'

Joseph Kotarek
Branch Chief, Toxicology

Division of Chemistry and
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OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K251674

Device Name
Fenom Flo™ FeNO Monitoring System

Indications for Use (Describe)

Fenom Flo™ FeNO Monitoring System is a portable, non-invasive device to measure fractional exhaled nitric oxide (FeNO) in human breath. FeNO is increased in some airway inflammatory processes, such as asthma, and decreases in response to anti-inflammatory treatment. Fenom Flo measures fractional exhaled nitric oxide (FeNO) according to guidelines established by the American Thoracic Society.

Measurement of FeNO by Fenom Flo is a non-invasive quantitative method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of therapeutic effect in patients with elevated FeNO levels. FeNo measurements are to be used as an adjunct to established clinical assessments. Fenom Flo is suitable for adults and children ages seven years and older.

Fenom Flo should be used in a point-of-care healthcare setting under professional supervision. Fenom Flo should not be used in critical care, emergency care, or anesthesiology.

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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MGC DIAGNOSTICS®

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510(k) Summary, K251674

November 26, 2025

Submitted by:

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Contact Person:

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Proprietary or Trade Name: Fenom Flo™ FeNO Monitoring System

Model Number: 8000

Common Name: FeNO Monitoring System

Classification: Breath Nitric Oxide Test System, 21 CFR 862.3080, MXA

Predicate Device: K213611, Fenom Pro™

Intended Use/Indications for Use:

Fenom Flo™ FeNO Monitoring System is a portable, non-invasive device to measure fractional exhaled nitric oxide (FeNO) in human breath. FeNO is increased in some airway inflammatory processes, such as asthma, and decreases in response to anti-inflammatory treatment. Fenom Flo measures fractional exhaled nitric oxide (FeNO) according to guidelines established by the American Thoracic Society.

Measurement of FeNO by Fenom Flo is a non-invasive quantitative method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of therapeutic effect in patients with elevated FeNO levels. FeNo measurements are to be used as an adjunct to established clinical assessments. Fenom Flo is suitable for adults and children ages seven years and older.

Fenom Flo should be used in a point-of-care healthcare setting under professional supervision. Fenom Flo should not be used in critical care, emergency care, or anesthesiology.

Device Description:

Fenom Flo™ FeNO Monitoring System quantitatively measures fractional exhaled nitric oxide (NO), an important marker for airway inflammation in exhaled human breath.

The system consists of:

- A handheld FeNO monitoring device (hereafter referred to as “Fenom Flo Device” or “Device”) that houses a rechargeable lithium-ion battery, a nitric oxide sensor, and integrated pneumatics and electronics for breath analysis. The device supports secure wireless communication through dedicated hardware and firmware.
- A Point-Of-Care Application (hereafter referred to as a “POC App”) operating on a Windows platform serves as the primary interface for displaying FeNO scores in parts per billion (ppb). The POC App offers key features, including test initiation, viewing of current and historical results, quality control, adjustable settings, a patient tutorial, and activity and error tracking. The POC App operates on any healthcare provider’s (HCP’s) device running Windows 10 or 11. It is the HCP’s responsibility to ensure that the device on which the POC App is installed meets all necessary performance, security, and compatibility requirements.
- A single-patient use, non-sterile disposable mouthpiece with an antibacterial/antiviral filter to prepare the exhaled breath for the measurement. The manufacturer is Polytechnic Resources, and the FDA clearance reference is K042758.
- The power supply recharges the battery or enables the device to operate.

Principle of Operation:

The non-invasive, portable Fenom Flo device utilizes digital electrochemical sensor technology to measure exhaled nitric oxide (FeNO). A patient performs a breath maneuver by inhaling ambient air, then placing their mouth on the mouthpiece and exhaling into the device. The graphical user interface (GUI) provided through a connected software application (POC App) displays an indication of the patient’s breath flow rate, allowing the user to modulate their breath flow rate within acceptable limits. The NO sensor produces an electrochemical potential difference between the electrodes of the sensor and is proportional to the amount of NO in the breath sample.

The procedure is typically performed once per patient. However, if an error occurs during exhalation—such as improper flow rate or incorrect timing—the procedure may be repeated to ensure accurate results.

The Fenom Flo device provides a digital readout of the fractional concentration of exhaled nitric oxide (FeNO) in parts per billion (ppb).

User and Operational Environment Information:

The Fenom Flo is intended to be used by trained professionals within healthcare settings such as hospitals, clinics, and other pulmonary function and cardiorespiratory diagnostic environments.

Summary of Intended Use/Indications for Use of Device Compared to Predicate Device:

The intended use/indications for use statement for the subject device is almost identical to that of the predicate device. The intended patient population and intended user are the same for the subject and predicate devices.

<p align="center">Subject Device Fenom Flo™ FeNO Monitoring System (K251674)</p>	<p align="center">Predicate Device Fenom Pro (K213611)</p>
<p>Fenom Flo™ FeNO Monitoring System is a portable, non-invasive device to measure fractional exhaled nitric oxide (FeNO) in human breath. FeNO is increased in some airway inflammatory processes, such as asthma, and decreases in response to anti-inflammatory treatment. Fenom Flo measures fractional exhaled nitric oxide (FeNO) according to guidelines established by the American Thoracic Society.</p> <p>Measurement of FeNO by Fenom Flo is a non-invasive quantitative method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of therapeutic effect in patients with elevated FeNO levels. FeNO measurements are to be used as an adjunct to established clinical assessments. Fenom Flo is suitable for adults and children ages seven years and older.</p> <p>Fenom Flo should be used in a point-of-care healthcare setting under professional supervision.</p> <p>Fenom Flo should not be used in critical care, emergency care, or anesthesiology.</p>	<p>Fenom Pro is a portable, non-invasive device to measure fractional exhaled nitric oxide (FENO) in human breath. FENO is increased in some airway inflammatory processes, such as asthma, and decreases in response to anti-inflammatory treatment. Fenom Pro measures fractional exhaled nitric oxide according to guidelines established by the American Thoracic Society.</p> <p>Measurement of FENO by Fenom Pro is a non-invasive quantitative method to measure the decrease in FENO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of therapeutic effect in patients with elevated FENO levels. FENO measurements are to be used as an adjunct to established clinical assessments. Fenom Pro is suitable for adults and children 6 years and older.</p> <p>Fenom Pro should be used in a point-of-care healthcare setting under professional supervision.</p> <p>Fenom Pro should not be used in critical care, emergency care or in anesthesiology.</p>

Summary of Technological Characteristics of Device Compared to Predicate Device:

Technological Characteristics Comparison Table:

Characteristics	Subject Device Fenom Flo™ FeNO Monitoring System (K251674)	Predicate Device Fenom Pro (K213611)	Comparison
Test Principle	Amperometric Sensor	Amperometric Sensor	Same
Design	Hand held portable	Desktop	Similar
Measurement Mode	6 second and 10 second breath maneuver	6 second and 10 second breath maneuver	Same
Detection Level	5 ppb	10 ppb	Similar
Measurement Range	5-300 ppb	10-200 ppb	Similar
Repeatability	2.5 ppb for values ≤50 ppb, 5% of measured values > 50 ppb	5 ppb for values ≤50 ppb, 10% of measured values > 50 ppb	Similar
Precision	<5 ppb NO for concentrations ≤50 ppb. <10% for NO concentrations >50 ppb.	<5 ppb NO for concentrations ≤50 ppb. <10% for NO concentrations >50 ppb.	Same
Accuracy	< ±5 ppb NO for concentrations ≤50 ppb. < ±10% for NO concentrations >50 ppb.	< ±5 ppb NO for concentrations ≤50 ppb. < ±10% for NO concentrations >50 ppb.	Same
Linearity	Slope 1.0 ± 0.05 r2 ≥ 0.998	Slope 1.0 ± 0.05 r2 ≥ 0.998	Same
Analysis Time	Approximately 27 seconds	Approximately 30 seconds	Similar
Power Supply	100-240V, ~50-60 Hz	100-240V, ~50-60 Hz	Same

Non-clinical Performance:

Non-clinical performance testing was conducted to verify that the Fenom Flo FeNO Monitoring System meets its design specifications, functional requirements, and intended use. These tests were performed in accordance with applicable standards and internal protocols, and they include electrical safety, electromagnetic compatibility (EMC), software verification and validation, mechanical integrity, and environmental testing as appropriate to the device's risk classification and use environment. Key performance characteristics evaluated include accuracy, repeatability, reliability, and response time. Bench testing confirmed that the device meets or exceeds all specified acceptance criteria and supports its claimed indications for use. The following list includes relevant standards that were used to establish the performance and functionality of the Fenom Flo device and its predicate, and were also utilized to support the overall evaluation.

- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- Breath Nitric Oxide Test System - Class II Special Controls Guidance Document for Industry and FDA Staff, Document issued on: July 7, 2003
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-2 Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 62366-1:2015+AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices
- ISO 14971: 2019 Medical devices - Applications of risk management to medical devices
- TIR57:2016 Principles for medical device security - Risk management.
- CLSI EP05-A3 (R2019) Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- ISTA 3A2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.

Clinical Performance

The clinical performance of the Fenom Flo FeNO Monitoring System was evaluated by measuring changes in fractional exhaled nitric oxide (FeNO) levels in subjects with uncontrolled, non-steroid-treated asthma, both before and after corticosteroid therapy. The **P10 study** was conducted at 13 clinical sites across the United States.

The P10 study demonstrated the substantial equivalence of the Fenom Flo to the Fenom Pro by confirming its clinical effectiveness in detecting statistically significant and clinically meaningful changes in FeNO levels following corticosteroid treatment. These changes were further supported by statistically significant, concordant, and clinically meaningful improvements across all major asthma efficacy variables in subjects aged seven years and older. The clinical study was conducted in accordance with the following guidelines and regulations:

- ATS Recommendations for Standardized Procedures for the Online and Offline Measurement of Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide, Am JRespir Crit Care Med, 2005; 171: 912–930.
- ISO 14155:2020– Clinical investigation of medical devices for human subjects – Good clinical practice.
- U.S. Code of Federal Regulations (21 CFR § 50) – Protection of Human Subjects.

Comparison to Predicate Devices and Conclusion:

The subject device, Fenom Flo FeNO Monitoring System, is identical in many ways to its predecessor, Fenom Pro.

While there are some technological characteristics that have slight differences, these differences do not raise new questions of safety or efficacy, as demonstrated by clinical and bench testing.

The clinical trial confirms substantial equivalence between the devices by demonstrating the clinical effectiveness for the statistically significant and clinically meaningful change in FeNO after corticosteroid therapy, which was also accompanied by statistically significant, concordant, and clinically meaningful improvements in all major asthma efficacy variables across all age ranges (seven years and older).

The Analytical Summary and bench testing data provided in this submission demonstrate that the Fenom Flo device meets or exceeds the performance of the predicate device (K213611) in the following areas:

1. Accuracy
2. Precision, Repeatability, and Carryover Effects
3. Linearity
4. Limit of detection
5. Interference from other gases
6. Exogenous testing
7. Environmental Testing (Barometric Pressure, Temperature and Humidity)
8. Device Operating Life
9. Packaged Device Shelf Life
10. Effects from Shipping
11. Exogenous Interference Study
12. Software validation
13. Usability and Human Factors Study
14. Cybersecurity testing
15. Biocompatibility
16. Electrical, Mechanical, Thermal Safety
17. EMC testing
18. Wireless Coexistence Testing

Based on the totality of clinical, analytical, usability, safety and software testing data, the Fenom Flo FeNO Monitoring System fulfills its intended use and is substantially equivalent to the predicate device

Conclusion:

In conclusion, MGC Diagnostics submits this 510(k) to support a substantial equivalence determination for Fenom Flo. This device demonstrates substantial equivalence to the predicate device based on the same intended use, plus the differences in technological characteristics do not raise different questions of safety and effectiveness. With the data and references in this 510(k) submission, the subject device is demonstrated to be at least as safe and effective as the legally marketed predicate device, per section 513(i) of the FD&C Act.