June 7, 2023

CAIRE Diagnostics Inc.
Ryan Leard
Chief Operating Officer
7020 Koll Center Parkway Suite 110
Pleasanton, California 94566

Re: K213611
Trade/Device Name: Fenom Pro
Regulation Number: 21 CFR 862.3080
Regulation Name: Breath Nitric Oxide Test System
Regulatory Class: Class II
Product Code: MXA
Dated: November 1, 2022
Received: November 2, 2022

Dear Ryan Leard:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k213611

Device Name
Fenom Pro

Indications for Use *(Describe)*
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.

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.

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

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

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510(k) SUMMARY

The assigned 510(k) number is: k213611

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: 05-JUN-2023

Applicant:
Name: CAIRE Diagnostics Inc.
Address: 7020 Koll Center Parkway, Suite 110
Pleasanton, CA 94566
Phone: (925) 433-0725
Email: ryan.leard@caireinc.com
Contact: Mr. Ryan Leard, Chief Operating Officer

Device name- trade name and common name, and classification

Trade name: Fenom Pro
Common Name: Breath nitric oxide test system
Classification: 21 CFR Part 862.3080

Predicate device:

Trade name: Fenom Pro™ Nitric Oxide Test
Predicate Manufacturer: Spirosure Inc.
Predicate 510(k) Clearance: K182874

Device Description

Fenom Pro is a non-invasive point-of-care breath analyzer for the quantitative measurement of fractional exhaled nitric oxide (FENO) in expired human breath.

Fenom Pro is comprised of four major components. The main unit contains a touch screen interface for the user and houses the nitric oxide sensor and pneumatics needed to sample the patient's breath. The patient exhales into the Fenom Pro though a single use disposable mouthpiece which is attached to the handpiece. The handpiece is connected to the main unit via a breath tube.

For testing, the patient inhales to total lung capacity and then slowly exhales into the mouthpiece for 6 or 10 seconds, depending on the mode of operation. Approximately 28 seconds after a successful breath maneuver, the FENO concentration is displayed in parts per billion (ppb) on the device touch screen. The device has a daily quality control procedure to ensure consistent device performance.

Intended Use / Indications for Use

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.

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.

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

Technological Similarities and Differences to the Predicate

The following Substantial Equivalence Chart describes similarities and differences between Fenom Pro and the predicate.

Substantial Equivalence Chart

Comparison	Subject Device Fenom Pro™ v2	Predicate Device Fenom PRO™ (K182874)	Difference
Class	Class II	Class II	Same
Regulation Number	21 CFR 862.3080	21 CFR 862.3080	Same
Product Code	MXA	MXA	Same
FDA Branch	Toxicology/Chemistry (75)	Toxicology/Chemistry (75)	Same
Result Type	Quantitative	Quantitative	Same
Test Locale	Point-of-Care, Professional	Point-of-Care, Professional	Same
Sensor Calibration	Factory Calibrated	Factory Calibrated	Same
Measurement Range	10-200 ppb NO	10-200 ppb NO	Same
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 r^2: ≥ 0.998	Slope: 1.0 ± 0.05 r^2: ≥ 0.998	Same
Detection Level	10 ppb	10 ppb	Same
Analysis Time	Approximately 30 seconds	Approximately 30 seconds	Same
Power Supply	100-240V, ~50-60Hz	100-240V, ~50-60Hz	Same
Breath Sample Conditioning	None	Reduced humidity	Different
Test Principle	Amperometric Sensor Technology	Potentiometric Sensor Technology	Different
Measurement Mode	6 second and 10 second breath maneuver	10 second breath maneuver	Different

Description of Nonclinical Data

Studies were performed to evaluate performance with regards to the specificity (interference), precision, accuracy, linearity, effect of temperature and humidity, detection limit and stability of the candidate device.

Description of Clinical Data

Clinical studies were performed to evaluate the clinical precision and clinical accuracy of the candidate device.

Conclusions:

Based on the information provided in this 510(k), the Fenom Pro is substantially equivalent to the predicate and raises no new issues of safety and effectiveness. The clinical and non-clinical testing performed demonstrates that the proposed device met all test specifications and is safe and effective for its intended use.