



September 11, 2025

Bosch Healthcare Solutions GmbH
Jeannette Stroh
Regulatory Affairs Manager
Alte Bundesstrasse 50
Waiblingen, 71332
Germany

Re: K243926
Trade/Device Name: Vivatmo pro-S
Regulation Number: 21 CFR 862.3080
Regulation Name: Breath Nitric Oxide Test System
Regulatory Class: Class II
Product Code: MXA
Dated: July 30, 2025
Received: July 31, 2025

Dear Jeannette Stroh:

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. Digitally signed by
KOTAREK -S JOSEPH A. KOTAREK -S
Date: 2025.09.11
14:41:20 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief
Division of Chemistry and
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K243926

Device Name

Vivatmo pro-S

Indications for Use (Describe)

Vivatmo pro-S nitric oxide test 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 often decreases in response to anti-inflammatory treatment. Measurement of FeNO by Vivatmo pro-S is a 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.

Vivatmo pro-S is suitable for children, approximately 7-17 years, and adults 18 years and older. Testing using the Vivatmo pro-S should only be done in a point-of-care healthcare setting under professional supervision. Vivatmo pro-S 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.

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Bosch Healthcare Solutions GmbH
Applicant Address	Alte Bundesstrasse 50 Waiblingen 71332 Germany
Applicant Contact Telephone	+49 173 3565637
Applicant Contact	Ms. Jeannette Stroh
Applicant Contact Email	Jeannette.Stroh@de.bosch.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Vivatmo pro-S
Common Name	Breath nitric oxide test system
Classification Name	System, Test, Breath Nitric Oxide
Regulation Number	862.3080
Product Code(s)	MXA

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233775	Vivatmo pro	MXA

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Vivatmo pro-S system is a automated, non-invasive (in-vitro diagnostic) medical device for professional environment for the quantitative measurement of FeNO (fractional exhaled Nitric Oxide) in human breath. Measurement of changes in the fractional nitric oxide concentration in expired breath aids in evaluating a patient's response to anti-inflammatory therapy, as an adjunct to establish clinical and laboratory assessments of inflammatory processes such as asthma. FeNO is recommended by the American Thoracic Society (ATS) in the diagnosis of eosinophilic airway inflammation and in determining the likelihood of responsiveness to anti-inflammatory pharmacological therapy in individuals with chronic respiratory symptoms possibly due to airway inflammation [ATS, 2011].

The Vivatmo pro-S device consists of the following main elements:

- Vivatmo pro-S handheld which holds the measuring module with electronics, display and a battery including software to drive the handheld.
- Vivatmo pro Oxycap/Vivatmo me Oxycap, which is a disposable mouthpiece to prepare the exhaled air for the measurement
- Vivatmo pro Level 0, a disposable mouthpiece to facilitate a measurement with 0 ppb FeNO for QC purpose (optional)

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Vivatmo pro-S nitric oxide test 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 often decreases in response to anti-inflammatory treatment. Measurement of FeNO by Vivatmo pro-S is a 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.

Vivatmo pro-S is suitable for children, approximately 7-17 years, and adults 18 years and older.

Testing using the Vivatmo pro-S should only be done in a point-of-care healthcare setting under professional supervision. Vivatmo pro-

S should not be used in critical care, emergency care or in anesthesiology.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The predicate device (Vivatmo pro) has identical indications for use as the device in this 510(k) submission (Vivatmo pro-S).

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The measurement principle of Vivatmo pro-S is identical to the predicate Vivatmo pro. It is based on a Chemical field effect transistor (Chem-FET). The nitrogen dioxide molecules are adsorbed on the sensor layer and the change in the binding energy creates an electrical signal, which is transferred into a quantifiable measurement signal. The nitrogen dioxide is converted from the Nitric oxide in the breath by a potassium permanganate converter in the disposable mouthpiece.

The predicate Vivatmo pro additionally has a base station for visualization of the breathing maneuver and data storage. Measurement takes place in the handheld that is identical for Vivatmo pro and Vivatmo pro-S (identical performance data).

Sample type (Exhaled human breath), test result (quantitative), sensor calibration (factory calibration), intended use setting (Point of care healthcare setting under professional supervision) and user age (children 7-17, adults) are identical for Vivatmo pro-S and the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

As non-clinical tests, EMC testing was performed. The EMC test report covers both devices, the Vivatmo me and the Vivatmo pro-S.

Cybersecurity testing was performed via penetration testing for Vivatmo me and the predicate device (Vivatmo pro), which are representatives of identical handhelds to the subject device Vivatmo pro-S. Further non-clinical tests were not necessary for the subject device Vivatmo pro-S as the performance data is identical to the predicate device Vivatmo pro. Please refer to substantial equivalence discussion attached to this submission.

Clinical tests were not necessary for the subject device Vivatmo pro-S as the performance data are identical to the predicate device Vivatmo pro. Please refer to substantial equivalence discussion attached to this submission.

Vivatmo pro-S is a modified version of the Vivatmo pro. The minor differences do not alter the intended diagnostic effect and do not impact the safety and effectiveness of the device.