510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K243926

B Applicant

Bosch Healthcare Solutions GmbH

C Proprietary and Established Names

Vivatmo pro-S

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MXA	Class II	21 CFR 862.3080 - Breath Nitric Oxide Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:
Modification to previously cleared device.

B Measurand:
Fractional exhaled nitric oxide

C Type of Test:
Chemical field effect transistor (Chem-FET)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Regardless of displayed measured results, monitor signs or symptoms of chest tightness, shortness of breath, coughing or wheezing for decisions about treatment. Do not use the device for subjects suffering from acute upper or lower respiratory infection disease or with current serious medical conditions (other than asthma).

Vivatmo pro-S should not be used in critical care, emergency care or in anesthesiology. The following conditions can influence correct measurement of results and shall be avoided: smoking or tobacco consumption for at least 1 hour before the measurement, eating or drinking at least 1 hour before the measurement, especially nitrate rich food (e.g., spinach), strenuous exercise, use of rescue inhaler or leukotriene modifier 1 h before measurement.

The device is not indicated for children under 7 years of age including infants, or by patients who are unable to understand and execute the instructions given by healthcare providers, as measurement requires patient cooperation.

D Special Instrument Requirements:

Vivatmo pro-S

IV Device/System Characteristics:

A Device Description:

The Vivatmo pro device is comprised of the following main components:

1. A Vivatmo pro-S handheld which holds the measuring module with electronics, display and a battery including software to drive the handheld.
2. A Vivatmo Oxycap, which is a disposable mouthpiece to prepare the exhaled air for the measurement. It is available in two different pack sizes:
    a. Vivatmo pro Oxycap (50 pieces)
    b. Vivatmo me Oxycap (5 pieces)

3. A Vivatmo pro Level 0 is a disposable mouthpiece with filters, desiccant and reagent to remove NO to facilitate a measurement with 0 ppb FeNO for QC purposes.

B Principle of Operation:

Vivatmo pro-S nitric oxide test is a portable, non-invasive device to measure fractional exhaled nitric oxide (FeNO) in human breath.

The measurement procedure of the Vivatmo pro-S generates the fraction of the exhaled breath (FeNO). The last 3 second fraction of a 10 second exhalation is evaluated for average NO concentration. The exhalation flow is controlled to 50 ml/s ±5 ml/s at an applied pressure of 10 to 20 cm H2O.

The measurement method of Vivatmo pro-S is Chemical field effect transistor (Chem-FET). The measurement sample is internally taken after a bypass time period and directly forwarded onto the sensor. 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 Nitric oxide in the breath by a potassium permanganate converter in the disposable mouthpiece.

NO2 is measured using Chem-FET detection with NO2 molecules accumulated to a sensitive layer changing the electrical field of the capacitor. The drop of voltage is proportional with the number of NO2 molecules accumulated.

C Instrument Description Information:

1. Instrument Name:

   Vivatmo pro-S

2. Specimen Identification:

   The healthcare professional assists the patient, who performs the test in real-time and is identified by patient name.

3. Specimen Sampling and Handling:

   The user obtains a breath sample by having the subject exhale into the device.

4. Calibration:

   The manufacturer performs calibration for each Vivatmo pro-S device. Recalibration by the user is not needed.

5. Quality Control:
   QC is recommended weekly or after 50 measurements.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Vivatmo pro

B Predicate 510(k) Number(s):
K233775

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243926	K233775
Device Trade Name	Vivatmo pro-S	Vivatmo pro
General Device Characteristic Similarities		
Intended Use/Indications For Use	Device intended to measure fractional exhaled nitric oxide (FeNO) in human breath	Same
Sample Type	Exhaled human breath	Same
Intended Use Setting	Point-of-care healthcare setting under professional supervision	Same
Measurement range	5– 300 ppb NO	Same
Detection Limit	5 ppb NO	Same
Analysis Time	Approximately 5 seconds	Same
Number of measurements	5000 measurement trials	5000 measurement trials
General Device Characteristic Differences		
Power source	4 AAA batteries 1.5 V	Rechargeable Li-ion battery 3.6 V
Base station	N/A	Part of Vivatmo pro system
PC Connection	N/A	Ethernet and WLAN through Basestation

VI Standards/Guidance Documents Referenced:

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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Established in k233775 and not impacted by the modifications.

2. Linearity:

   Established in k233775 and not impacted by the modifications.

3. Analytical Specificity/Interference:

   Established in k233775 and not impacted by the modifications.

4. Assay Reportable Range:

   Established in k233775 and not impacted by the modifications.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The device is traceable to commercially available material.

6. Detection Limit:

   Established in k233775 and not impacted by the modifications.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Established in k233775 and not impacted by the modifications.

9. Carry-Over:

   Established in k233775 and not impacted by the modifications.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

Not applicable. The assay can be run using breath samples only.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Clinical Accuracy: Established in k233775 and not impacted by the modifications.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

In the labeling, the sponsor instructs the user to refer to the Official ATS clinical practice guideline: interpretation of exhaled nitric oxide levels (FENO) for clinical applications.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.