January 2, 2020

NuvoAir AB
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K183089
Trade/Device Name: Air Next
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: December 20, 2019
Received: December 30, 2019

Dear Yolanda Smith:

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); 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,

for Michael Ryan
Division Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K183089

Device Name
Air Next

Indications for Use *(Describe)*
Air Next is intended to be used by:
Healthcare professionals trained to perform spirometry tests on patients of age ≥ 5 years old, > 10 kg and ≥ 110 cm.

Air Next is intended to perform basic lung function and spirometry testing. The actual diagnosis shall be done by a healthcare professional in hospital and clinical settings.

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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# 510(k) Summary

## SPONSOR


| | |
|---|---|
| Company Name: | NuvoAir AB |
| Company Address | 17 Riddargatan<br>Stockholm 114 57<br>Sweden |
| Telephone: | +46 725538233 |
| Contact Person: | Vanessa Caldeira |


Summary Preparation Date: December 31, 2019

## DEVICE NAME

| | |
|---|---|
| Trade Name: | Air Next |
| Common/Usual Name: | Spirometer |
| Classification Name: | Diagnostic Spirometer |
| Regulation Number**:** | 21 CFR 868.1840 |
| Product Code: | BZG |
| Device Class: | Class II |
| Reviewing Panel: | Anesthesiology |

## PREDICATE DEVICE

Legally Marketed Equivalent Device

| Predicate | K Number | Brand Name | Company |
|---|---|---|---|
| Primary | K072979 | Spirobank G | MIR Medical International Research |
| Reference | K061712 | Spirobank II | MIR Medical International Research |

## DEVICE DESCRIPTION

Air Next is intended to perform basic lung function and spirometry testing. It measures parameters such as the forced expiratory volume in 1 sec (FEV1) and the forced vital capacity (FVC) in a forced expiratory maneuver. These measures can be used for detection, assessment and monitoring of diseases affecting the lung function, such as bronchial Asthma, COPD and Cystic Fibrosis.

Air Next is a hand-held spirometer, weighing only 75g and it is powered by 2 AAA alkaline 1.5V batteries. It consists of 3 main components: the Air Next device, the NuvoAir disposable turbine (delivered in one package) and the Air Next mobile application downloadable from Apple's and Google's Play Stores. The package includes one Air Next device, one NuvoAir disposable turbine through which the user can start using the Air Next, two AAA 1.5V alkaline batteries, one user manual and one cotton bag to carry the device. Dimensions of the Air Next are 98 x 62 x 26 mm, which can be seen in the engineering drawing in the attachments.

## DEVICE INDICATIONS FOR USE

Air Next is intended to be used by:

Healthcare professionals trained to perform spirometry tests on patients of age ≥ 5 years old, > 10 kg and ≥ 110 cm.

Air Next is intended to perform basic lung function and spirometry testing. The actual diagnosis shall be done by a healthcare professional in hospital and clinical settings.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a dentist or physician.

## COMPARISON OF TECHNICAL CHARACTERISTICS

Predicate Product Comparison Table

| Feature | Subject Device | Primary Predicate K072979 | Similarities and Differences |
|---|---|---|---|
| Manufacturer | NuvoAir | M.I.R. Medical International Research | |
| Product Code | BZG | BZG | Same |
| Regulation No, | 21 CFR 868.1840 | 21 CFR 868.1840 | Same |
| Indications for Use | Air Next is intended to be used by:<br>Healthcare professionals trained to perform spirometry tests on patients of age ≥ 5 years old, > 10 kg and ≥ 110 cm.<br>Air Next is intended to perform basic lung function and spirometry testing.<br>The actual diagnosis shall be done by a healthcare professional in hospital and clinical settings. | The Spirobank G spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infants and neonates. It can be used in any setting. | Similar indications for the use. The only difference between subject device and predicate device is that the Indications for Use in the subject device includes also weight and height while Predicate device only uses age as a limitation. Subject device is not for use in home setting. |
| Use Environment | Hospital and clinical settings. | All settings that include clinical and home use | Different<br>Use is limited to clinical settings only. |
| Intended User | Trained health care professionals perform spirometry testing on Adults and pediatric patients over 5 years old | People of all ages, excluding infants and neonates. | Different |
| Prescription only | Yes | Yes | Same |

| Feature | Subject Device | Primary Predicate K072979 | Similarities and Differences |
|---|---|---|---|
| Principle of Operation | The Air Next is designed to work with NuvoAir disposable turbine. When performing a spirometry test, the user exhales into the turbine. The airflow generated is forcing a propeller to rotate inside the turbine. The Air Next registers the speed of the spinning propeller by counting the rotations with a digital infrared interruption sensor. The algorithm in the firmware inside the Air Next device then converts the rotations into airflow measured in liters per second.<br><br>The device is also tested against B.T.P.S. (body temperature and pressure with saturated water vapor) conditions as prescribed by ATS guidelines and the results are well within range. | Spirobank G is a powerful and compact measurement device, intended for use by a respiratory specialist or by a suitably trained generalist.<br>Two different types of turbine sensors can be used with the device, one is reusable and one is single-patient disposable. A disposable mouthpiece is required in order to connect a subject to the spirometer.<br><br>The flow and volume measurement sensor is a digital turbine, based on the infrared interruption principle.<br><br>Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.<br><br>Spirometry test interpretation is based on the Forced Vital Capacity (FVC) test and is based on the ATS standard. | Same |
| Technical Feature | | | |
| Flow Sensor | Bidirectional turbine with infrared interruption | Bidirectional turbine with infrared | Same |
| Physical Characteristics | | | |
| Energy Type | Two AAA 1.5V Alkaline batteries | 9V Alkaline battery | Different |
| Display | Touchscreen on smartphone or tablet | Touchscreen / LCD and membrane | Different |
| Operating Environment | T: min +10°C/max +40° C<br>RH: min 10 %/max 95 % ALT: max 2000 m | Temperature: MIN + 10 °C, MAX + 40 °C;<br>Humidity: MIN 10% RH; MAX 95%RH | Same |
| Physical Size | Light hand-held device | Light hand-held device | Same |

| Feature | Subject Device | Primary Predicate K072979 | Similarities and Differences |
|---|---|---|---|
| Weight | 75g | 160g | Different |
| Technical Specifications | | | |
| Volume accuracy | ±3% of reading or ±0.050 L, whichever is greater | ±3% of reading or ±0.050 L, whichever is greater | Same |
| Volume range | Up to 10 L | Up to 10 L | Same |
| Flow range | 0-15L/s | 0-16 L/s | Similar |
| Flow accuracy | ±5% or 200 mL/s | ±5% or 200 mL/s | Same |
| Flow resistance | <0.5 cmH2O/L/s | <0.5 cmH2O/L/s | Same |
| Connectivity | Bluetooth | Bluetooth of USB | Same - Bluetooth |
| Measured parameter | | | |
| Forced vital capacity | FVC | FVC | Same |
| Volume expired in the first | FEV0.75, FEV1, FEV3, FEV6 | FEV0.75, FEV1, FEV3, FEV6 | Same |
| Ratio between volume expired in a certain time period and FVC | FEV/FVC (FER) for 0.75 /1 /3 / 6 | FEV/FVC (FER) for 0.75 /1 /3 / 6 | Same |
| Peak expiratory flow | PEF | PEF | Same |
| Forced expiratory flow between the first 25% and 75% of the FVC | FEF25-75 (MEF) | FEF25-75 (MEF) | Same |
| Volume inspired in the first second of the test | FIV1 | FIV1 | Same |
| Forced inspiratory volume | FIVC | FIVC | Same |
| Peak inspiratory flow | PIF | PIF | Same |

| Feature | Subject Device | Primary Predicate K072979 | Similarities and Differences |
|---|---|---|---|
| Forced inspiratory flow in the first 25% and 75% of the FIV | FIF25-75 (MIF25-75) | FIF25-75 (MIF25-75) | Same |
| Ratio between FEV1 and FEV6 | FEV1/FEV6 | FEV1/FEV6 | Same |
| Forced expiratory flow at 50% of FVC divided by FVC | FEF50/FVC | FEF50/FVC | Same |
| Forced inspiratory flow in the first 25% and 75% of the FIV | FIF25-75 (MIF25-75) | FIF25-75 (MIF25-75) | Same |
| Ratio between FEV1 and FEV6 | FEV1/FEV6 | FEV1/FEV6 | Same |
| Forced expiratory flow at 50% of FVC divided by FVC | FEF50/FVC | FEF50/FVC | Same |
| Force inspiratory flow at first second device forced inspiratory volume | FIV1/FIVC (FIR) | FIV1/FIVC (FIR) | Same |
| Forced expiratory time | FET | FET | Same |
| Maximum voluntary ventilation | N/A | MVV (ind) | Different |
| **Device Use Design** | | | |
| Used with PFT filter and / or mouthpiece | Mouthpiece Disposable | Mouthpiece Disposable or Reusable | Same for Disposable Turbine – See reference predicate chart below |
| Coaching | Display of flow-time curves, timer and effort during test | Display of volume-time and flow-volume curves | Different |
| Feedback on test quality | Yes - according to ATS guidelines | Yes – Traffic lights for interpretation | Similar |
| Graphic display | Yes- on App | Yes on device screen | Different |
| Safety Standards | | | |

| Feature | Subject Device | Primary Predicate K072979 | Similarities and Differences |
|---|---|---|---|
| Applied Standards for safety | Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2 | Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2 | Same |
| Applied Standards for safety | Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2 | Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2 | Same |
| Biocompatibility | According to ISO 10993-1 | According to ISO 10993- 1 | Same |
| Meets ATS accuracy requirements | Yes | Yes | Same |

## Reference Device

The disposable turbine used in Air Next device is manufactured and purchased from MIR Medical International Research and is cleared under K061712. The disposable turbine is supplied in its final finished form and is identical to the reference predicate device.

## PERFORMANCE TESTING

The following performance data were provided in support of the substantial equivalence determination.

### Safety testing

| Testing Standard | Test Description | Result |
|---|---|---|
| IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 | Medical electrical equipment – Part 1: general requirements for basic safety and essential performance | Pass |
| IEC 60601-1-6:2010, AMD1:2013 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | Pass |
| IEC 62366:2007 | Medical devices – Application of usability engineering to medical devices | Pass |
| IEC· 60601-1-2:2014 (ED. 4) | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests | Pass |

### Biocompatibility

#### Handle and Exterior Surface

The Handle and Exterior is designed to be a surface device for intact skin with limited contact A – limited (≤24 h). The following testing was performed:

Based on the device categorization outlined above, the nature of the material contact and the guidance given in ISO 10993-1, the tests deemed appropriate for the device materials were selected as shown in the table below.

| Biological Effect | Test | Compliance Standard |
|---|---|---|
| Cytotoxicity | Mem Elution | ISO10993-5 |
| Irritation or Intracutaneous Reactivity | Intracutaneous Injection Test | ISO10993-10 |
| Irritation and Sensitization | Kligman Maximization test | ISO10993-10 |

**Disposable Turbine**

NuvoAir Turbines are disposable turbines intended for single use for a period of less than 24hr. NuvoAir has provided a declaration statement from the legal manufacturer, MIR, stating that the NuvoAir disposable turbine for Air Next Spirometer (ref. code 910007) is identical in its final finished form to the disposable turbine legally marketed and identified with code 910004 and that this turbine is in turn legally US-marketed Spirobank II (K061712).

## Additional Testing Standards

- ATS/ERS 2005 guideline
- ISO 14971:2007 - Application of risk management to medical devices.
- IEC 62366:2007 + A1:2014. *Application of usability engineering to medical devices.*
- ISO 62304:2006/A1:2015: Medical device software. Software life-cycle processes
- EN ISO 26782: 2009, Anesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans
- EN ISO 23747:2015, Anesthesia and respiratory equipment – Peak expiratory flowmeters for the assessment of pulmonary function in spontaneously breathing humans
- FCC Part 15, Subpart B, C

Clinical testing was not performed with this device.

**Substantial Equivalence Conclusion:**

Based upon the foregoing performance testing and comparison to the legally marketed predicate devices for indications for use, technology, and performance we believe we have demonstrated that the Air Next is substantially equivalent and as safe and as effective as the predicate device. Furthermore, the differences versus the predicate device do not impact safety and effectiveness.