August 28, 2023

Roundworks Technologies Private Limited
% Ankur Naik
Managing Director
IZiel Healthcare
14, Hadapsar Industrial Estate, Hadapsar
Pune, Maharashtra 411013
India

Re: K222525
Trade/Device Name: alveoair Digital Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: July 27, 2023
Received: July 27, 2023

Dear Ankur Naik:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222525

Device Name
alveoair Digital Spirometer

Indications for Use *(Describe)*
The alveoair Digital Spirometer is intended to conduct basic lung function and spirometry testing on patients aged ≥ 22 years by healthcare professionals or clinicians in any healthcare environment. The use of an alveoair Digital Spirometer is not intended for use during patient transport.

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.

510(k) Summary

510(K) summary of safety and effectiveness for alveoair Digital Spirometer is provided in accordance with 21 CFR 807.92.

Date:	28 August 2023
Submitter (Owner):	Prashant Patel Founder & CEO Roundworks Technologies Private Limited. Office No. B 302, Building No. B, 3rd floor, GO Square, Survey No. 249/250, Above Surya Electronics, Wakad, Pune – 41104, India. P: +91 7507776273 Email: prashant@alveo.fit
510(k) Contact Person:	Ankur Naik Managing Director IZiel Healthcare 14, Hadapsar Industrial Estate, Hadapsar, Pune – 411013, India. P: +91 72762 2555 M: +91 7069553814 Email: ankur.naik@izielhealthcare.com
Device Trade Name:	alveoair Digital Spirometer
Regulation Number:	21 CFR 868.1840
Review Panel:	Anesthesiology
Device Class:	Class II
Product Code:	BZG
Predicate Device:	Air Next (K183089)
Reference device:	Spirobank G (K072979)

Device Description

The alveoair Digital Spirometer is used to test lung function in people of all ages ≥ 22 years. It is intended to be used by healthcare professionals or clinicians in any healthcare environment. The alveoair Digital Spirometer was designed, developed, and manufactured at Roundworks Technologies Pvt Ltd. The model number is indicated below:

Model Number	Model Name	Model Description
ALV002	alveoair Digital Spirometer	Digital Spirometer to measure lung function parameters

The alveoair Digital Spirometer system includes:

- alveoair Digital Spirometer

- alveoMD mobile application
- alveofit API Cloud server backend

The alveoair Digital Spirometer is intended to be used and compatible only with the flowMIR disposable turbine and cardboard mouthpiece manufactured by the Medical International Research s.r.l. The accessories are 510k cleared under K061712 and it is single-use disposable. Roundworks Technologies Pvt Ltd recommends the user to purchase the single-use disposable flowMIR turbine on their own. One sample piece of the flowMIR (Ref. code: 910004) disposable turbine sensor and disposable cardboard mouthpiece is provided in the packaging. Roundworks recommends that the user purchase the same model turbine and mouthpiece from Medical International Research s.r.l. for further use.

The alveoair digital spirometer is available in two different colors. The internal components, software, and function remain the same for both devices. The only difference is the color of the case; one is completely black and the other is a combination of black and white.

The alveoair Digital Spirometer is used in combination with a turbine and mouthpiece. It utilizes a smartphone with a dedicated mobile application (alveoMD) and a cloud server (alveoFit) to view and store spirometer readings. This portable spirometer operates on the principle of infrared interruption. To perform a test, the user inhales and exhales air through the mouthpiece, which then flows into the turbine. The turbine's propeller rotates in both clockwise and counterclockwise directions, depending on the airflow. The firmware within the device calculates a series of volume and flow coordinates, in liters with respect to time in seconds, every time an interrupt data is received from the IR sensor. This process continues for 20 seconds or until the flow change calculated is less than 0.025 liters per second. When the patient inhales/exhales air into the spirometer during the standard or full loop tests. Once the test is completed, all coordinates are transferred to the mobile application using BLE. From there, the data is uploaded to the alveofit API Cloud server via the internet.

For the alveoMD app, an internet connection is required to initiate the spirometry test. The alveoFit cloud server takes in the coordinates to calculate all lung parameters. Once the process is completed, a test report will be generated and displayed in the alveoMD mobile application. The internal program performs all calculations for measurements to meet ATS/ERS guideline standardization of spirometry 2019.

Intended Use / Indications for Use

The alveoair Digital Spirometer is intended to conduct basic lung function and spirometry testing on patients aged ≥ 22 years by healthcare professionals or clinicians in any healthcare environment. The alveoair Digital Spirometer is not intended for use during patient transport.

Comparison to predicate devices

Table 1: Comparison to Predicate Device

Comparable Properties	Subject Device	Predicate Device (K183089)	Reference Device (K072979)	Comparison Results
Product name	alveoair Digital Spirometer	Air Next	Spirobank G	Not applicable
Manufacturer	Roundworks Technologies Pvt Ltd.	NuvoAir AB	M.I.R. Medical International Research	Not applicable
Classification Name	Spirometer, Diagnostic	Spirometer, Diagnostic	Spirometer, Diagnostic	Identical
Regulation number	21 CFR 868.1840	21 CFR 868.1840	21 CFR 868.1840	Identical
Product code	BZG	BZG	BZG	Identical
Product Class	Class II	Class II	Class II	Identical
Intended Use / Indications for Use	The alveoair Digital Spirometer is intended to conduct basic lung function and spirometry testing on patients aged ≥ 22 years by healthcare professionals or clinicians in any healthcare environment. The alveoair Digital Spirometer is not intended for use during patient transport.	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 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.	Substantially Equivalent

Comparable Properties	Subject Device	Predicate Device (K183089)	Reference Device (K072979)	Comparison Results
		The actual diagnosis shall be done by a healthcare professional in hospital and clinical settings.		
Target Population	Patients aged ≥ 22 years old.	Patients of age ≥ 5 years old, > 10 kg, and ≥ 110 cm.	All ages, excluding infants and neonate.	Substantially Equivalent
Intended User	Health care Professionals or clinicians	Trained health care Professionals.	People of all ages, excluding infants and Neonates.	Substantially Equivalent
Prescription / Over the counter	Prescription	Prescription	Prescription	Identical
Use Environment	Doctor's office or hospitals, and clinics	Hospital and clinical settings	It can be used in any setting	Identical
Principle Operation	The alveoair Digital Spirometer is designed to be used in combination with a turbine and a mouthpiece. It functions as a portable spirometer, operating on the infrared interruption principle. The airflow generated by the user's breath forces a propeller to rotate inside the turbine. The direction of the turbine's rotation, whether clockwise or anti-	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	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. The flow and volume measurement sensor is a digital turbine,	Substantially Equivalent

Comparable Properties	Subject Device	Predicate Device (K183089)	Reference Device (K072979)	Comparison Results
	clockwise, depends on the flow direction. To measure the respiratory parameters accurately, the spirometer's sensor tracks the propeller's rotations and calculates its spinning speed concerning time. The device's firmware processes this data and computes a series of volume and flow coordinates in liters per second whenever an interrupt data is received from the IR sensor.	interruption sensor. The algorithm in the firmware inside the Air Next device then converts the rotations into airflow measured in liters per second. 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	based on the infrared interruption principle. Spirometry test interpretation is based on the Forced Vital Capacity (FVC) test and is based on the ATS standard.	
Technical Features				
Flow Sensor	Bidirectional digital turbine with infrared interruption	Bidirectional turbine with infrared interruption	Bidirectional turbine with infrared interruption	Identical
Physical Characteristics				
Size	112 x 55 x 21mm;	98 x 62 x 26mm	109 x 49 x 21mm	Substantially Equivalent
Weight	Central unit 76g (including batteries)	75g	160g	Substantially Equivalent
Energy Type	2 x 1.5V, AAA batteries	2 x 1.5V, AAA Alkaline	9V Alkaline battery	Identical to Predicate Device

Comparable Properties	Subject Device	Predicate Device (K183089)	Reference Device (K072979)	Comparison Results
		batteries		
Display	The touchscreen on smartphone or tablet	The touchscreen on smartphone or tablet	Touchscreen / LCD and membrane	Identical to Predicate Device
Operating Environment	Temp: MIN: +10°C, MAX: +40°C Humidity: MIN: 10% RH, MAX: 95% RH	Temp: MIN: +10°C, MAX: +40°C RH: MIN: 10%, MAX: 95% ALT: MAX: 2000 m	Temp: MIN: +10°C, MAX: +40°C. Humidity: MIN: 10% RH, MAX: 95% RH	Identical
Technical Specifications				
Volume range and accuracy	Up to 8L ±2.5% of reading or ±0.050 L, whichever is greater	Up to 10L ±3% of reading or ±0.050 L, whichever is greater	Up to 10L ±3% of reading or ±0.050 L, whichever is greater	Substantially equivalent as the subject device is compliant to the requirements of American Thoracic Society (ATS) Standardization of Spirometry 2019 update and ISO 26782: 2009
Flow range and accuracy	0 - 14 L/s ±10% or 0.17 L/s	0-15 L/s ±5% or 200 mL/s	0-16 L/s ±5% or 200 mL/s	Substantially equivalent as the subject device is compliant to the requirements of ISO 23747:2015
Flow resistance	<0.5 $cmH_2O/L/s$	<0.5 $cmH_2O/L/s$	<0.5 $cmH_2O/L/s$	Identical
Connectivity	Bluetooth	Bluetooth	Bluetooth of USB	Identical

Comparable Properties	Subject Device	Predicate Device (K183089)	Reference Device (K072979)	Comparison Results
IP Rating	IP22	IP32	IP22	Identical to Reference Device
Turbine and Mouthpiece	Single-use and disposable	Single patient use and disposable	Single patient use and disposable	Identical
Material of Turbine and Mouthpiece	Polycarbonate and Pure cellulose or paper	Polycarbonate and Pure cellulose or paper	unknown	Identical to Predicate Device
Shelf life	2 years	Unknown	Unknown	Substantially equivalent
Service Life	5 years	10 years	Around 10 years	Substantially equivalent
Measured Parameter				
Measured Parameters	FVC, FEV0.25, FEV0.5, FEV0.75, FEV1, FEV3, FEV6, FEV1/FVC, FEV0.5/ FVC, FEV3/FVC, FEV0.75/FVC, PEF, FEF2575, FEF10, FEF25, FEF40, FEF50, FEF60, FEF75, FEF80, FEF50/FVC, FEV1/FEV6, FET, BEV, FIVC, PIF, FIF25, FIF50, FIF75, and Estimated Lung Age	FVC, FEV0.75, FEV1, FEV3, FEV6, FEV/FVC (FER) for 0.75 /1/3 / 6, PEF, FEF25-75, FEF50/FVC, FEV1/FEV6, FET, FIVC, PIF, and FIF25-75 (MIF25-75),	FVC, FEV0.75, FEV1, FEV3, FEV6. FEV/FVC (FER) for 0.75/1 /3 / 6, PEF, FEF25-75, FEF25, FEF50, FEF75, FEF50/FVC, FEV1/FEV6, FET, Evol, FIVC, PIF, FIF25-75 (MIF25-75), and ELA.	Similar parameters for subject, predicate and reference devices. Differences do not affect the safe and effective use of the subject device

Performance data

The alveoair digital spirometer complies with the following standards:

Electrical Safety and EMC:

1) ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
2) IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
3) IEC 60601-1-2:2014+AMD1:2020 CSV Consolidated version Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Software:

1) Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
2) IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes.

Cybersecurity:

1) Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Management of Cybersecurity.

Biocompatibility:

- Handheld Subject Device Contact Type and Duration: Surface Intact skin, limited duration (≤24 hr)
- Turbine and mouthpiece contact the patient's gas pathway (cleared K061712)

1) ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
2) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
3) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices — Part 10: Tests for skin sensitization.
4) ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation.

Risk Management:

1) ISO 14971:2019 Medical devices — Application of risk management to medical devices.

Labels & IFU:

1) ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.
2) ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices — Information to be supplied by the manufacturer.

Performance:

1) ISO 26782:2009 Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time-forced expired volumes in humans.
2) ISO 23747:2015 Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans.
3) ATS/ERS 2019 guideline Standardization of Spirometry 2019 Update an Official American Thoracic Society and European Respiratory Society Technical Statement.

Usability:

1) Guidance for Applying Human Factors and Usability Engineering to Medical Devices

Conclusion

All the above details collectively demonstrate that alveoair digital spirometer is substantially equivalent to the predicate device.