June 12, 2023

Inofab Saglik Teknolojileri A.S
% Ray Kelly
Consultant
Arazy Group Consultants Inc.
3422 Leonardo Lane
New Smyrna Beach, Florida 32168

Re: K213754
Trade/Device Name: SpiroHome Ultrasonic Spirometer, SpiroHome Clinic, SpiroHome Personal
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: January 17, 2023
Received: January 23, 2023

Dear Ray Kelly:

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
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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)*
K213754

Device Name
SpiroHome Ultrasonic Spirometer, SpiroHome Clinic, SpiroHome Personal

Indications for Use *(Describe)*
SpiroHome is intended to be used by adults and children over 5 years old in physician's offices, clinics and home setting to conduct basic lung function and spirometry testing.

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.

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510(k) Summary
21 CFR 807.92

In accordance with 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

I. Submitter Information

Submitter Name:

Inofab Health Sağlik Teknolojileri A.S
Üniversiteler Mahallesi,
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ODTÜ Teknokent Silikon Blok No:17/115,
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Phone: +90 312 988 03 08

Contact Person: Ray Kelly
Date Prepared: June 09, 2023

II. Device Information:

Name of Device: SpiroHome Ultrasonic Spirometer,
SpiroHome Clinic, SpiroHome Personal
Common Name: Spirometer
Classification Name: Diagnostic Spirometer (21 CFR 868.1840)
Regulatory Class: II
Product Code: BZG

III. Predicate Device:

GoSpiro, K163249

IV. Reference Device:

EasyOne Air Spirometer, K161536

V. Device Description

The SpiroHome Ultrasonic Spirometer (SUS) is a portable spirometer designed to perform pulmonary function tests in patients over the age of 5 in office (clinical) and home settings. The SpiroHome spirometer is used together with a SpiroWay mouthpiece that is inserted into and lines the entire airway of the device. SpiroHome derives pulmonary function data from airflow measurements taken by its ultrasonic sensors during a spirometry test. All of the information recorded by the device is displayed on the relevant SpiroHome app running on a Bluetooth-connected device. The pulmonary function test (PFT) data recorded by the SpiroHome device during a spirometry test is also compared against the patient's predicted values which are

obtained from internationally accepted PFT equations. The user interfaces with the SpiroHome app during the entire use of the SpiroHome spirometer.

The associated accessories include: SpiroWay mouthpiece

VI. Indication for Use:

SpiroHome is intended to be used by adults and children over 5 years old in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing.

VII. Comparison of technological characteristics with the predicate and reference device:

The subject device has the same spirometry functions with the same test types, test parameters and utilize the same interpretation algorithms as the predicate device, however, the ultrasonic sensor technology used in the subject device is different to that of the predicate device which utilizes a turbine-based sensor. The subject device has the same technological characteristics with regards to spirometry testing as the reference device, in particular the same sensor technology is used for spirometry testing. The differences in sensor measurement technology do not raise concerns of safety and effectiveness for the subject device.

The subject device and predicate device both use Bluetooth-connected devices as displays in comparison to the reference device which has a touch-enabled display on the device. Each model of the subject device operates with its own respective application version whereas the predicate device has only one application with which it operates.

The subject device and predicate device both use off-the-shelf standard batteries whereas the reference device uses a rechargeable battery pack.

Each model of the subject device is used with its own respective mouthpiece model. The personal model of the subject device is used with a reusable mouthpiece and the clinic model is used with a disposable mouthpiece. The predicate device mouthpiece is constructed from both reusable and disposable components, and the reference device is used only with disposable mouthpieces. Design verification and validation demonstrates that the SpiroHome spirometer used in combination with the SpiroWay mouthpiece provides the same spirometry test results as the predicate and reference devices used in combination with their respective mouthpieces and is therefore substantially equivalent to the predicate and reference devices.

Table 1. Comparison of subject device attributes to predicate device and reference device

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
Indications for Use	Intended to be used by adults and children over 5 years old in physician's offices, clinics and home setting to conduct basic lung function and spirometry testing.	Intended to be used by adults and children over 5 years old in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. It is a single-patient use device.	The EasyOne Air spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients over 4 years old. The EasyOne Air spirometer is used by general practitioners, specialists, and health care professionals, in hospitals and clinics, in pharmacies, and in clinical settings in occupational medicine.	Identical for subject and predicate.
Common Name	Spirometer, Diagnostic	Spirometer, Diagnostic	Spirometer, Diagnostic	Identical
Regulation	868.1840	868.1840	868.1840	Identical
Product Code	BZG	BZG	BZG	Identical
Classification	II	II	II	Identical
Review Panel	Anesthesiology	Anesthesiology	Anesthesiology	Identical
Intended User	HCP or patient	HCP or patient	HCP	Identical for subject and predicate.
Environment of Use	Clinic or home	Clinic or home	Clinic	Identical for subject and predicate.
Principle of Operation	Spirometer is designed for pulmonary function tests. It is a portable spirometer capable of generating Pulmonary Function Test (PFT) data based on the air flow and volume. The	Spirometer is designed for pulmonary function tests. It is a portable spirometer capable of generating Pulmonary Function Test (PFT) data based on the air flow and volume. The	Spirometer is designed for pulmonary function tests. It is a portable spirometer capable of generating Pulmonary Function Test (PFT) data based on the air flow and volume. The	Identical for subject and predicate and similar to reference device.

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
	device measures a patient's lung function values and compares it to their predicted values (obtained from internationally accepted lung function test equations). The portable spirometer pairs to smart devices running the associated apps.	device measures a patient's lung function values and compares it to their predicted values (obtained from internationally accepted lung function test equations). The portable spirometer pairs to smart devices running the associated apps.	device measures a patient's lung function values and compares it to their predicted values (obtained from internationally accepted lung function test equations). The portable spirometer has on-device screen display.	
Conditions of Use	Spirometer is available for home use or clinical use. Clinic use is indicated for healthcare professionals (HCPs) to use with patients (pediatric between the ages of 5-21 and adults over the age of 21) who may have been diagnosed with a chronic pulmonary disease. Clinic use is intended to be used in a clinical setting multiple times a day by multiple patients. The home user, after it is prescribed by a clinical/professional, will be used by patients at home. Home users are (pediatric between the ages of 5-21 and adults over the age of	Spirometer is available for home use or clinical use. Clinic use is indicated for healthcare professionals (HCPs) to use with patients (pediatric between the ages of 5-21 and adults over the age of 21) who may have been diagnosed with a chronic pulmonary disease. Clinic use is intended to be used in a clinical setting multiple times a day by multiple patients. The home user, after it is prescribed by a clinical/professional, will be used by patients at home. Home users are (pediatric between the ages of 5-21 and adults over the age of 21) who may have	Spirometer is available for only clinical use. Clinic use is indicated for healthcare professionals (HCPs) to use with patients (pediatric between the ages of 4-21 and adults over the age of 21) who may have been diagnosed with a chronic pulmonary disease. Clinic use is intended to be used in a clinical setting multiple times a day by multiple patients. Users need to interact with the device to assemble the device by inserting batteries, turning on the device, and go through the device set up	Identical for subject and predicate.

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
	21) who may have been diagnosed with a chronic pulmonary disease. Patients or their care providers/legal guardians will use the device multiple times a day by a single patient. Users need to interact with the device to assemble the device by inserting batteries, turning on the device, and go through the device set up procedure in the app. Users then perform spirometry test by breathing into the device and receive feedback on their performance though the app. Users will clean the device as instructed.	been diagnosed with a chronic pulmonary disease. Patients or their care providers/legal guardians will use the device multiple times a day by a single patient. Users need to interact with the device to assemble the device by inserting batteries, turning on the device, and go through the device set up procedure in the app. Users then perform spirometry test by breathing into the device and receive feedback on their performance though the app. Users will clean the device as instructed.	procedure. Users then perform a spirometry test by breathing into the device and receive feedback on their performance though the app. Users will clean the device as instructed.	
Software	Mobile Medical App (MMA)	Mobile Medical App (MMA)	Mobile Medical App (MMA)	Identical
Software LOC	Moderate	Moderate	Moderate	Identical
Bluetooth	Yes	Yes	Yes	Identical
Used with PFT filter and / or mouthpiece	Mouthpiece Disposable or Reusable	Mouthpiece Disposable and Mouthport Reusable	Mouthpiece Disposable	Similar for subject and predicate. Predicate mouthpiece has a reusable (mouthport) and disposable component and is

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
				for single- patient use. Subject device has reusable mouthpiece for home use and a disposable mouthpiece for clinic use, both are for single-patient use. Reference device has only a single-patient disposable mouthpiece. No concerns raised regarding subject device safety or effectiveness due to mouthpiece differences.
Configuration	Hand-held, portable	Hand-held, portable	Hand-held, portable	Identical
Patient Population	Over 5 years old	Over 5 years old	Over 4 years old	Identical for subject and predicate.
Sensor Technology	Transit-time Ultrasound	Turbine	Transit-time Ultrasound	Identical for subject and reference device.
Recalibration	Not required	Required	Not required	Identical for subject and reference.
Measured Parameters	FVC, FEV0.75 , FEV1 , FEV3 , FEV6 , FEV0.75/FVC , FEV1/FVC , FEV3/FVC , FEV6/FVC , PEF	FVC, FEV0.75 , FEV1 , FEV3 , FEV6 , FEV0.75/FVC, FEV1/FVC, FEV3/FVC , FEV6/FVC, PEF, MMEF, FEF25 , FEF50 , FEF75 , FEF25-75 ,	*BEV, EOTV, FEF10, FEF25, FEF25-75, FEF25-75/FVC, FEF40, FEF50, FEF50/FVC, FEF60, FEF75, FEF80, FET,	Similar parameters for subject, predicate and reference devices. Differences do not affect the safe and effective use

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
	, MMEF , FEF25 , FEF50 , FEF75 , FEF25-75 , MET25-75 , FEV0.75/FEV6 , FEV1/FEV6 , FEF50/FVC, MMEF/FVC, FET, BEV, FIV1 , FIVC, PIF, FIF25-75 , FIV1/FIVC, R50 (FEF50/FIF50), VC, VCin , VCex , ERV, IRV, IC, Rf , VT, MVV, MVV6 , MVVtime	FIV1 , FIVC , PIF, FIF25-75, FIF25 , FIF50 , FIF75, MET25-75, FEV0.75/FEV6 , FEV1/FEV6 , FEF50/FVC , FIV1/FIVC, R50 (FEF50/FIF50) , FET, MVV	FET25-75, FEV.25, FEV.5, FEV.5/FVC, FEV.75, FEV.75/FVC, FEV1, FEV1/FEV6, FEV1/FIV1, FEV1/FVC, FEV3, FEV3/FVC, FEV6, FIF25, FIF50, FIF50/FEF50, FIF75, FIV.25, FIV.5, FIV1, FVC, FVC6, FVC, FVC6, MEF20, MEF25, MEF40, MEF50, MEF60, MEF75, MEF90, MIF25, MIF50, MIF75, MMEF, PEF, PEFT, t0, MVV, MVV6, MVVtime, Rf, ERV, IC, IRV, Rf, VC, VCex, VCin, VCmax, VT	of the subject device.
Power	2 x AAA Alkaline and Rechargeable Batteries	Rechargeable lithium-ion batteries	Rechargeable battery pack	The difference in power sources between devices does not raise concerns of safety or effectiveness of the subject device as validated by the electrical safety, performance, and EMC testing .
Air Resistance	48.54 Pa*s/L (Highest Expiratory Impedance)	137 Pa*s/L	*0.3 cm H2O/L/s at 16 L/s	Differences in dynamic air resistance between devices based on design

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
				differences and does not raise concerns over device safety and effectiveness of the subject device.
Volume Range & Accuracy	0-10 L, ± 2.5% or ± 0.050 L	0-8 L, ± 3% or ± 0.050 L	*±12 L, *±2% or 0.050 L	Difference between volume range and accuracy between devices are minor, the subject device meets permissible margins given in ATS guidelines and ISO 286782.
Flow Range & Accuracy	0 - 14 L/s, ±10% or ± 170 mL/s	0 - 14 L/s, ±5% or 200 mL/s	*±16 L/s *±2% or 0.020 L/s (except PEF) *±5% or 0.200 L/s PEF accuracy	Difference between flow range and accuracy between devices are minor, the subject device conforms to permissible margins given in ISO 286782.
Display Type/Size	Mobile app	Mobile app	Touch-enabled display on device	Identical for subject and predicate devices.
Flow-Volume Loop	During test and test review	During test and test review	*During test and test review	Identical
Volume-Time Curve	During test and test review	During test and test review	*During test and test review	Identical
Dimensions W x D x H	110mm x 40.8m x 63.3mm	88.9mm x 114.3mm x 50mm	*87mm x 155mm x 36mm	Subject device is smaller in overall volume than both

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
				predicate and reference devices. Difference in size does not raise concerns for subject device safety and effectiveness as demonstrated in usability and performance tests.
Weight	90g (with batteries)	300g (with batteries)	*356 g (with batteries)	Subject device weighs less than both predicate and reference devices. Difference in weight does not raise concerns for subject device safety and effectiveness as demonstrated in usability and performance tests.
Connection to patient	Mouthpiece	Mouthpiece	Mouthpiece	Identical
Storage Temperature	-20°C to 60°C	*-20°C to 70°C	*-20°C to 50°C	Minor differences. Differences do not affect the safety and effectiveness of the subject device as demonstrated in product testing.
Storage Humidity (RH)	5% to 85%	15% to 95%	*5% to 90%	Minor differences. Differences do not affect the safety and effectiveness

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
				of the subject device as demonstrated in product testing.
Operational Temperature	15°C to 35°C	17°C to 35°C	*0°C to 40°C	Minor differences. Differences do not affect the safety and effectiveness of the subject device as demonstrated in product testing.
Operational Humidity (RH)	30% to 85%	30% to 75%	*5% to 90%	Minor differences. Differences do not affect the safety and effectiveness of the subject device as demonstrated in product testing.
Expected Service Life	5 years	Not Provided	*7 years	Similar for subject and reference device, difference does not affect the safety or effectiveness of the subject device.
Water Ingress Protection	IP22	IP22	Not Provided	Identical for subject and predicate.
Electrical safety	Meets IEC 60601-1	Meets IEC 60601-1	Meets IEC 60601-1	Identical
EMC safety	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Meets IEC 60601-1-2	Identical
Home use	Meets IEC 60601-1-11	Meets IEC 60601-1-11	Not Provided	Identical for subject and predicate device.
Biocompatibility	Meets ISO 10993-1, ISO 10993-5, ISO	Meets ISO 10993-1, ISO 10993-5,	ISO 10993-1, ISO 10993-5, ISO 10993-10,	Subject, predicate and reference

Attribute	Subject Device Spirohome	Predicate Device GoSpiro (K163249)	Reference Device (K161536)	Similarities / Differences
	10993-10, ISO 10993-11, ISO 18562- 1, ISO 18562-2, ISO 18562-3, USP 43-NF 38 (2020) <85> and EP 2.6.14 (EP 10.3)	ISO 10993-10, Volatile Organic Compounds (VOC), CO, CO2, Ozone, and PM2.5 testing	ISO 10993-18, ISO/FDIS 18562-2, ISO/FDIS 18562-3	devices meet requirements of ISO 10993-1 and ISO 18562-1. Subject device also meets pyrogen and LAL testing requirements.

VII. PERFORMANCE DATA

The SpiroHome Ultrasonic Spirometer was tested against criteria for:

- Functional Requirements
    - ATS 2019 / ERS waveform simulator testing
    - ISO 26782:2009
    - ISO 23747:2015
    - High Altitude Performance
    - Flow Resistance
- Electrical Requirements
    - AAMI ANSI ES 60601-1
    - IEC 60601-1-11
    - IEC 60601-1-2
- Biocompatibility

Contact Type and Duration: Surface Contact, Mucosa, Externally Communicating, Tissue; permanent (>30 days)

    - ISO 10993-1
    - ISO 10993-3
    - ISO 10993-5
    - ISO 10993-10
    - ISO 10993-11
    - ISO/FDIS 18562-1
    - ISO/FDIS 18562-2
    - ISO/FDIS 18562-3
- Shipping Requirements, Packaging and Distribution
    - ASTM D4332
    - ASTM D7386
    - ASTM F1886/F1886M
    - ISO 17664
    - ISO 11737-1
- Cleaning
    - ISO 17664
    - AAMI TIR30
    - AAMI TIR12
    - ASTM E2314
    - ISO 15883-1
    - ISO 11737-1
    - ISO/TS 15883-5
- Software and System Verification and Validation
    - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
    - IEC 62304
- Human Factors Study
    - Guidance for Applying Human Factors and Usability Engineering to Medical Devices
    - AAMI/ANSI HE75:2009

- ANSI/AAMI/IEC 62366-1:2015

VIII. CONCLUSIONS

Based upon the foregoing performance testing and comparison to the legally marketed predicate device, and reference device, for indications for use, technology, and performance, we believe we have demonstrated that the SpiroHome Spirometer is substantially equivalent to the predicate device.