October 19, 2023

NDD Medizintechnik AG
Andreas Senn
Director Quality, RA & CA
Technoparkstrasse 1
Zurich, 8005
Switzerland

Re: K230178
Trade/Device Name: EasyOne Sky Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: September 5, 2023
Received: September 6, 2023

Dear Andreas Senn:

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); 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.

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230178

Device Name
EasyOne Sky spirometer

Indications for Use *(Describe)*
The EasyOne Sky spirometer is intended to conduct diagnostic spirometry testing on adults and pediatric patients starting at age 4.
The EasyOne Sky spirometer is used by general practitioners, specialists and healthcare professionals.
The EasyOne Sky is used in hospitals, clinics, pharmacies, in clinical settings, and in occupational medicine.

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

In accordance with 21 CFR 807.92 the following information is provided for EasyOne Sky spirometer.

ADMINISTRATIVE INFORMATION

Date prepared	October 18, 2023
Submission type:	Traditional 510(k)
Purpose of 510(k):	Introduction of a new device
Submitter	NDD Medizintechnik AG Technoparkstrasse 1 CH-8005 Zürich Note: NDD stands for New Diagnostic Design
Official Contact	Andreas Senn Director Quality, RA & CA Ndd Medizintechnik AG, Switzerland Phone : +41 44 512 65 41 e-mail : ase@ndd.ch
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DEVICE NAME AND CLASSIFICATION

Trade name:	EasyOne Sky Spirometer
Common name:	Diagnostic Spirometer
Regulation number:	21 CFR 868.1840
Classification name:	Diagnostic spirometer

Regulatory class:	Class II
Product Code:	BZG

PREDICATE DEVICE

Primary Predicate Device: EasyOne Air Spirometer, K161536

Reference Devices: GoSpiro, K163249, K202837

INDICATIONS FOR USE

The EasyOne Sky spirometer is intended to conduct diagnostic spirometry testing on adults and pediatric patients starting at age 4. The EasyOne Sky spirometer is used by general practitioners, specialists and healthcare professionals. The EasyOne Sky is used in hospitals, clinics, pharmacies, in clinical settings, and in occupational medicine.

DEVICE DESCRITION

The product **EasyOne Sky** (EOS) is a medical electrical equipment for spirometry testing. It consists of the hand-held **TrueFlow Sensor FT** (SeNe) comprising an ultrasonic flow sensor that conducts air flow measurements, the application **EasyOne Mobile** (EOMA), and the breathing mouthpiece **EasyOne FlowTube** (EOFT). The EOS can be used with the optional accessories EasyOne Filter FT and a nose clip.

Key functions:

- The key function of the **TrueFlow Sensor FT** (SeNe) is to acquire patient flow data by measuring transit-times of ultrasonic pulses and to send data wireless (via Bluetooth Low Energy) to the host system. The measurements and data transmission are performed by the firmware of the SeNe defined as MDSW with clinical functions.
- The key function of the application **EasyOne Mobile** (EOMA) is to trigger the start of the measurement with the TrueFlow Sensor FT, to communicate with it and to visualize the data received from it.
- The **EasyOne FlowTube** (EOFT) is an individually packaged, single-patient-use breathing tube and is intended to canalize patient breath through the flow sensor tube. The EOFT is an essential accessory to EOS.

The host system, for example a smartphone, where EOMA runs on, is not part of the EOS medical electrical equipment.

Figure 1: Visualization of the EOS system including the TrueFlow sensor FT with the inserted EasyOne Flow Tube and the application EasyOne Mobile installed on a mobile device.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE

Criteria	**EasyOne Sky** Subject Device	**EasyOne Air** Primary Predicate Device	**Predicate comparison results**
510(k) number	K230178	K161536	-
Manufacturer	NDD Medizintechnik AG	NDD Medizintechnik AG	Same
Regulation number	21 CFR 868.1840	21 CFR 868.1840	Same
Classification name	Diagnostic Spirometer	Diagnostic Spirometer	Same
Product Code(s)	BZG	BZG	Same
Regulatory Class	II	II	Same
Intended use	Diagnostic spirometry testing	Diagnostic spirometry testing	Same
Indications for use	The EasyOne Sky spirometer is intended to conduct diagnostic spirometry testing on adults and pediatric patients starting at age 4. The EasyOne Sky spirometer is used by general practitioners, specialists and healthcare professionals. The EasyOne	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	Substantially Equivalent

	Sky is used in hospitals, clinics, pharmacies, in clinical settings, and in occupational medicine.	and clinics, in pharmacies, and in clinical settings in occupational medicine.	
Type of use	Prescription use	Prescription use	Same
Patient population	Adults and pediatric patients over 4 years old	Adults and pediatric patients over 4 years old	Same
Users	General practitioners, specialists, healthcare professionals	General practitioners, specialists, healthcare professionals	Same
Use environment	Hospital and clinical settings Pharmacies Occupational medicine	Hospital and clinical settings Pharmacies Occupational medicine	Same
Single patient use	No. Accessories are for single patient use only	No. Accessories are for single patient use only	Same
Description	The EasyOne Sky spirometer is a hand-held battery powered device, which uses digital ultrasonic flow measurement technology for fast, accurate and reliable operation. The TrueFlow Sensor FT firmware performs the measurement and calculates the parameters in accordance with American Thoracic Society and European Respiratory Society requirements. The device transmits data to the EasyOne Mobile application over a Bluetooth connection to display the test results and further data management.	The EasyOne Air spirometer is a hand-held battery powered device, which uses digital ultrasonic flow measurement technology for fast, accurate and reliable operation. The EasyOne Air firmware performs the measurement and calculates the parameters in accordance with American Thoracic Society and European Respiratory Society requirements. The device has an integrated touchscreen to display the test results. Data can be transmitted to the EasyOne Connect PC Software via cradle or over a Bluetooth connection for further data management.	Similar
System components	Hand-held TrueFlow Sensor FT EasyOne Mobile application	Hand-held TrueFlow sensor with rechargeable battery Docking USB Cradle for charging and data transfer (EasyOne Connect Software) AC/DC power supply USB cables	Similar, both devices consist of a flow sensor and a software application to display and manage data. They differ in their power supply and other accessories.
Accessories for single patient use	Breathing Mouthpiece: EasyOne FlowTube	Breathing Mouthpiece: EasyOne FlowTube	Same

	Optional filter: EasyOne Filter FT	Optional filter: EasyOne Filter FT	
Software Requirements	Android, iOS Hard disk capacity minimum 250 MB	Embedded firmware	Similar software functionality but are different in implementation
Spirometry standards	Meets ATS/ERS/ISO waveform testing requirements	Meets ATS/ERS/ISO waveform testing requirements	Same
Forced expiratory vital capacity test (FVC)	FVC, FEV1, FEV0.75 (only shown for children ≤6yr), FEV1/FVC, FEV0.75/FVC (only shown for children ≤6yr), FET, PEF	FVC, FEV1, FEV.75, FEV1/FVC, FEV.75/FVC, FET, PEF	Same, Parameters for basic spirometry tests are the same as defined in ATS / ERS 2019 Table 9.
Flow volume loop test (FVL)	FVC, FEV1, FEV0.75, FEV1/FVC, FEV0.75/FVC, PEF, FET, FIVC	FVC, FEV1, FEV.75, FEV1/FVC, FEV.75/FVC, PEF, FET, FIVC	Same

Additional tests and parameters	FVC: additional parameter: - FEF25-75, FEF25, FEF50, FEF75 - MMEF, MEF75, MEF50, MEF25, (naming) FVL additional parameter: - PIF - FEF25-75, FEF25, FEF50, FEF75 - MMEF, MEF75, MEF50, MEF25, (naming)	FVC additional parameter: ATI, BEV, EOTV, FEF10, FEF25, FEF25-75, FEF25-75_6, FEF40, FEF50, FEF50/FVC, FEF50/VCmax, FEF60, FEF75, FEF75-85, FEF80, FET25-75, FEV.25, FEV.5, FEV.5/FVC, FEV.75/FEV6, FEV.75/VCmax, FEV1/FEV6, FEV1/FVC6, FEV1/VC, FEV1/VCmax, FEV3/FVC, FEV3/VCmax, FEV3, FEV6, FVC, MEF20, MEF25, MEF40, MEF50, MEF60, MEF75, MEF90, MMEF, MTC1, MTC2, MTC3, MTCR, PEFT, t0, VC, VCmax FVL additional parameter: ATI, BEV, CVI, E50/I50, EOTV, FEF10, FEF25, FEF25-75, FEF25-75_6, FEF40, FEF50, FEF50/FVC, FEF50/VCmax, FEF60, FEF75, FEF75-85, FEF80, FET25-75, FEV.25, FEV.5, FEV.5/FVC, FEV.75/FEV6, FEV.75/VCmax, FEV1/FEV6, FEV1/FIV1,FEV1/FIVC, FEV1/VC, FEV1/VCmax, FEV3/FVC,FEV3/VCmax, FEV3, FEV6, FIF25, FIF 25-75, FIF50, FIF50/FEF50, FIF75, FIV.25, FIV.5, FIV1, MEF20, MEF25, MEF40, MEF50, MEF60, MEF75, MEF90, MIF25, MIF50, MIF75, MMEF, MMIF, MTC1, MTC2, MTC3, MTCR, PEFT, PIF, t0, VC, VCmax MVV additional parameter: MVV, MVV6, MVVtime, Rf, VCext, VT SVC additional parameter: ERV, IC, IRV, Rf, VC, VCex, VCin, VCmax, VT	Additional parameters which go beyond basic spirometry testing according ATS / ERS 2019 recommendation differ between devices.

Measurement principle	Ultrasonic transit-time measurement (TrueFlow)	Ultrasonic transit-time measurement (TrueFlow)	Same
Measuring accuracy • Volume • Flow • Flow PEF	• ±2 % or 0.050L • ±2 % or 0.020L/s (except PEF) • ±5% or 0.2L/s	• ±2 % or 0.050L • ±2 % or 0.020L/s (except PEF) • ±5% or 0.2L/s	Same
Measuring range • Volume • Flow	0 - 8 L ±16 L/s	0 - 12 L ±16 L/s	The ranges of the subject device meet permissible margins given in ATS guidelines and ISO 26782.
Resolution	1 mL/s	1 mL/s	Same
Resistance	Less than 1.5 cm H_2O/L/s at 16L/s	Less than 1.5 cm H2O/L/s at 16L/s	Same
Dimensions L x H x B	111 x 84 x 33 mm	155 x 87 × 36 mm (6.1 x 3.4 × 1.4 in)	Similar
Weight	140 g without batteries	302 g (11 oz) without battery 356 g (13 oz) with battery	EasyOne Sky is smaller in weight
Display	No integrated display, data displayed on mobile device	Integrated LCD touchscreen 88.9 mm (3.5 in) diagonal size 320 × 240 pixels	Substantially Equivalent
Power supply	2x AA size alkaline batteries	Rechargeable lithium-ion battery (output 3.6 V) AC/DC power supply for charging (4.5 to 5,5 V)	Similar
Voltage	5V DC	4.5 V to 5.5 V	Similar
Power consumption	0.3 W	Up to 7.5 W	Similar
IP code	IP22	IP20	Similar
Hardware interface	None	USB 1.0/1.1, USB 2.0 (max. 100 mA)	Different
Wireless connection	Bluetooth Low Energy • Frequency range 2.4 GHz ISM band (2.402 – 2.480 GHz utilized) • Modulation GFSK (Gaussian frequency shift keying) • Output power -4 dBm	Bluetooth Low Energy • Frequency range 2.402 GHz to 2.480 GHz • Modulation GFSK, DQPSK, 8DPSK • Output power 15 dBm • QoS WMM and WMM Power Save Support	Same

Data management	EasyOne Mobile application	EasyOne Connect PC software	Similar, devices manage their acquired data with a separate data management software.
Export / Electronic Medical Records (EMR)	HL7, XML, GDT	HL7, XML, GDT	Same
Printing option	Yes, over network	Direct to printer or with EasyOne Connect PC software	Similar, different printer options
Lifetime	7 years	7 years	Same

The subject device EasyOne Sky has similar indications, intended use, target populations, technological characteristics, and materials as the predicate device EasyOne Air and reference device GoSpiro. The subject and the predicate device have the same fundamental design, use the same TrueFlow ultrasound measurement principle to and same EasyOne FlowTube breathing mouthpiece and optional EasyOne Filter FT accessories. The spirometer itself is reusable whereby accessories are single use devices and intended for single patient use only.

EasyOne Sky, EasyOne Air and GoSpiro spirometers all provide basic spirometry testing in accordance with ATS / ERS recommendations and guidelines.

The hand-held sensors TrueFlow Sensor FT and GoSpiro do not have a built-in display, they all require a separate device for displaying results. The EasyOne Sky and the GoSpiro are using an application for displaying data or graphics.

Any differences between EasyOne Sky and the predicate EasyOne Air do not raise questions concerning safety and effectiveness. Performance testing in accordance with applicable standards demonstrates that the EasyOne Sky is adequate for its intended use. The EasyOne Sky spirometer is therefore substantially equivalent to the predicate.

SUMMARY OF NON-CLINICAL TESTS

Test	Acceptance Criteria
Performance	Complies with spirometry standards ATS/ERS recommendation and guidelines, ISO 23747:2015 (Accuracy, Repeatability and Linearity) and ISO 26782:2009 (13 waveforms)
Cleaning, disinfection	Cleaning & disinfection validation support that there is no loss of functionality.
Biocompatibility	Biological Evaluation and toxicological risk assessment to evaluate device's biological safety for the intended use, in accordance with ISO 10993-series and FDA guidance. The EasyOne FlowTube and EasyOne Filter FT are in the breathing gas pathway. The EasyOne FlowTube has been introduced with K161536 and EasyOne Filter FT with K221250.

	Contact type: • Intact skin for TrueFlow Sensor FT • Intact skin, mucosa, and externally communicating tissue/bone/dentin device for EasyOne FlowTube Contact duration: Prolonged Considered endpoints per ISO 10993-1:2018 • ISO 10993-18:2020 Physical and/or chemical information • ISO 10993-5:2009 Cytotoxicity • ISO 10993-10:2021 Sensitization • ISO 10993-23:2021 Irritation or intracutaneous reactivity Gas path testing according to • ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways • ISO 18562-2:2017 Tests for emissions of particulate matter • ISO 18562-3:2017 Tests for emissions of volatile organic compounds (VOCs)
Electrical Safety, Electromagnetic Compatibility	Complies with • IEC 60601-1:2020 General Requirements for Basic Safety And Essential Performance • IEC 60601-1-2: 2020 Electromagnetic Disturbances • IEC 60601-1-6:2020 CSV Usability
Software, Cybersecurity	Software developed according to • IEC 62304:2006 and IEC 82304-1:2016 • Final Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005 • Final Guidance Off-The-Shelf Software Use in Medical Devices, September 2019 • Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2014 • Radio Frequency Wireless Technology in Medical Devices, August 2013

CONCLUSION

The subject device EasyOne Sky has similar indications, intended use, target populations, technological characteristics, and materials as the predicate devices. Non-clinical testing demonstrated that the proposed device is at least as safe and effective as the predicate. Therefore the subject device is substantially equivalent to the predicate device.