DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 22, 2017

Ndd Medizintechnik Ag
% Jerry Masiello
Operations Manager
Ndd Medical Technologies Inc.
300 Brickstone Square, Suite 604
Andover, Massachusetts 01810

Re: K161534
Trade/Device Name: Easyone Pro Respiratory Analysis System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: BTY
Dated: January 13, 2017
Received: January 23, 2017

Dear Jerry Masiello:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
161534

Device Name
EasyOne Pro Respiratory Analysis System

Indications for Use *(Describe)*
EasyOne Pro/LAB is designed for conducting lung function measurements in general or specialist practices or in hospitals.
EasyOne Pro/LAB can also be used in clinical settings in occupational medicine for performing lung function screenings or measurements.
EasyOne Pro/LAB is used to conduct lung function measurements on adults and children starting at age 4, except measurements of diffusing capacity of the lung based on CO (DLCO), which can be performed on adults and children starting at age 6.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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8 510(k) Summary

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

Submitter Information

Submitter name:	ndd Medizintechnik AG Technoparkstrasse 1 8005 Zurich, Switzerland
United States contact person:	Mr. Jerry Masiello Operations Manager ndd Medical Technologies, Inc
Phone:	(877) 904.0090 x11
Fax:	(978) 824.3853
Email:	jmasiello@nddmed.com
Type of Submission:	Traditional 510(k)
Date prepared:	July 20, 2016

Device Name

Proprietary name:	EasyOne Pro Respiratory Analysis System
Common name:	Pulmonary function testing device
Class	Class II according to 21 CFR 868.1890
Classification name:	Predictive pulmonary-function value calculator
Product code:	BTY
Regulation number:	868.1890

Predicate Device

Primary Predicate:
EasyOne Pro Respiratory Analysis System, model EasyOne Pro
K091428

Secondary Predicate:
EasyOne Pro Respiratory Analysis System, model EasyOne Pro LAB
K120635

Device Description

The EasyOne Pro Respiratory Analysis System consists of two different device models: EasyOne Pro and EasyOne Pro LAB.

The EasyOne Pro Respiratory Analysis System devices are pulmonary function testing devices. Both EasyOne Pro Respiratory Analysis System device models provide Spirometry and Single Breath CO Diffusion (DLCO) tests including Lung Volume Parameters. The device model EasyOne Pro LAB additionally provides the Nitrogen Multiple Breath Washout (MBW) method. The

EasyOne Pro Respiratory Analysis System devices meet the ATS recommendations for accuracy and precision for Spirometry, DLCO and MBW tests.

The EasyOne Pro Respiratory Analysis System devices can be used as a stand-alone system and can be connected to a network.

The EasyOne Pro Respiratory Analysis System devices use the following sensors: An ultrasonic flow sensor to measure flow velocity, volume and molar mass of the gases that the patient inhales and exhales; a molar mass sensor which determines the helium content of the respired air for the DLCO test and the nitrogen concentration for the multiple-breath washout (MBW) test; a CO sensor (EasyOne Pro) or a combined CO/CO_2 sensor (EasyOne Pro LAB) to determine CO and CO_2 content in breathing gas; a temperature and humidity sensor to collect environmental data.

The EasyOne Pro Respiratory Analysis System devices are used in combination with test gases (DLCO gas for DLCO tests and O_2 for MBW tests).

The EasyOne Pro Respiratory Analysis System devices are used in combination with the single-patient use breathing tube ndd Spirette. For DLCO and MBW tests, the additional single-patient use accessories, the ndd DLCO or FRC Barriettes, are used.

The single-patient use accessories prevent cross-contamination between patients. The Spirette prevents the passage of microorganisms into the inside of the flow sensor; the Barriettes prevent the passage of microorganisms into gas supply tubing.

Intended Use:

EasyOne Pro/LAB is designed for conducting lung function measurements in general or specialist practices or in hospitals.

EasyOne Pro/LAB can also be used in clinical settings in occupational medicine for performing lung function screenings or measurements.

EasyOne Pro/LAB is used to conduct lung function measurements on adults and children starting at age 4, except measurements of diffusing capacity of the lung based on CO (DLCO), which can be performed on adults and children starting at age 6.

Comparison of Technological Characteristics:

The modified device models of the EasyOne Pro Respiratory Analysis System have the same technological characteristics with regards to Spirometry, DLCO and MBW testing as the predicate devices.

Side-by-side comparison of technological characteristics

Description	**Currently marketed device Primary predicate device**	**Currently marketed device Secondary predicate device**	**Subject device**
Device identification	EasyOne Pro Respiratory Analysis System Model: EasyOne Pro K091428	EasyOne Pro Respiratory Analysis System Model: EasyOne Pro LAB K120635	EasyOne Pro Respiratory Analysis System Models: EasyOne Pro EasyOne Pro LAB K161534
Product code	BTY	BTY	BTY

Description	Currently marketed device Primary predicate device	Currently marketed device Secondary predicate device	Subject device
Intended Use (incl. target population)	System for pulmonary function testing on adults and children (over the age of 4 for spirometry lung function measurements and over the age of 6 for DLCO testing).	Identical	Identical
Target users	The EasyOne Pro Respiratory Analysis System is used by physicians, respiratory therapists or nurses in general or specialist practices or in hospitals. The EasyOne Pro Respiratory Analysis System can also be used in clinical settings in occupational medicine for performing lung function screenings or measurements in occupational medicine.	Identical	Identical
User interface	Resistive touch screen for data entry and display	Identical	Capacitive touch screen for data entry and display
Patient interface	EasyOne Pro: • Disposable breathing tube Spirette • Disposable barrier shield DLCO Barriette	EasyOne Pro LAB: • All identical In addition: • Disposable barrier shield FRC Barriette	Identical
Components	EasyOne Pro : • Main Unit (embedded computer, touch screen and monitor) • Handheld flow sensor • Breathing valve assembly (for DLCO and FRC tests) • DLCO gas mix supply • 100-240 VAC, 50/60 Hz power supply	EasyOne Pro LAB: • All identical In addition: • 100% O2 gas supply	Identical
Operating system	Microsoft Windows XP Embedded Microsoft Access database	Identical	Microsoft Windows 8 Embedded SQLite/Microsoft SQL server database

Description	Currently marketed device Primary predicate device	Currently marketed device Secondary predicate device	Subject device
Physical dimensions	270 mm x 335 mm x 270 mm (h x w x d)	Identical	Identical
Pulmonary Function Testing	EasyOne Pro : • Spirometry tests: FVC, FVL, SVC, MVV, Pre-post Bronchodilator • Single Breath CO Diffusion (DLCO) test including Lung Volume	EasyOne Pro LAB: • All identical In addition: • Nitrogen Multiple Breath Washout (MBW) test	Identical
Principle of operation	EasyOne Pro: All test types - measurement of patient air flow via ultrasonic transit time flow sensor. DLCO test - determination of in– and exhaled gas concentrations: CO gas concentration measured by infrared absorption with CO sensor. Helium tracer gas concentration measured by molar mass sensor.	EasyOne Pro LAB: All identical In addition: MBW test - determination of in- and exhaled gas concentrations: Nitrogen tracer gas concentration determined by a combination of molar mass measurement (molar mass sensor) and CO_2 measurement (CO/CO2 sensor).	Identical
Reported Spirometry parameters	FVC, FEV0.5, FEV1, FEV3, FEV6, FEV1/FVC, FEV3/FVC, FEV1/FEV6, FEF25%, FEF50%, FEF75%, FEF25-75%, FEF75-85%, PEF, FIVC, FIV0.5, FIF50%, PIF, FET, Vext, MVV, MTV, RR, AT, VC, ERV, IRV, TV	Identical	Identical
Reported Lung Volume parameters	EasyOne Pro: DLCO test: FRC, TLC, RV, RV/TLC, VT, f	EasyOne Pro LAB: All identical In addition - MBW test: FRC, TLC, RV, RV/TLC, LCI, VT, f	Identical
Reported DLCO parameters	DLCO, TLCO, DLadj, DLCO/VA, DLCO/VAadj, VA, VCin, BHT	Identical	Identical
Test gas requirements for DLCO test	Medical grade gas mix CO: 0.3 % Helium: 10 % Oxygen: 18 % - 25 % Nitrogen: balance	Identical	Identical

Description	Currently marketed device Primary predicate device	Currently marketed device Secondary predicate device	Subject device
Test gas requirements for MBW test	*(not applicable for EasyOne Pro)*	Oxygen 100 %	Identical
Flow sensor specification Flow range Volume accuracy Flow accuracy Flow resistance	 ±16 L/s Greater of ±2 % or 0.050 L Greater of ±2 % or 0.020 L/s <1.5 cm H_2O/L/s (at 12 L/s)	 Identical Identical Identical Identical	 Identical Identical Identical ~0.3 cm H_2O/L/s (at 12 L/s)
Molar mass sensor specification Type Range Resolution Accuracy	 Ultrasonic transit time 9 - 50 g/mol 0.02 g/mol ±0.01 g/mol	 Identical Identical Identical Identical	 Identical Identical 0.005 g/mol Identical
CO Sensor specification Type Range Resolution Accuracy	 Infrared absorption 0 - 0.35 % 0.0001 % ±0.001 %	 Identical Identical Identical Identical	 Identical Identical Identical Identical
CO2 Sensor specification Type Range Resolution Accuracy	*(not applicable for EasyOne Pro)*	 Infrared absorption 0 - 7 % 0.01 % ±0.1 %	 Identical 0 - 15% 0.005% ±0.05%
Tracer Gas Analysis for DLCO Tracer gas Type Range Resolution Accuracy	 Helium Molar mass sensor 0 - 50% He 0.01% He ±0.05% He	 Identical	 Identical
Tracer Gas Analysis for MBW Tracer gas Type Range Resolution Accuracy	*(not applicable for EasyOne Pro)*	 Nitrogen Molar mass sensor 0 – 100 % N_2 0.1 % N_2 ±0.2 % N_2	 Identical

The same single-patient use accessories – Spirette, DLCO Barriette and FRC Barriette – are used with the modified devices than with the predicate devices. The same materials in the patient gas path are used with the modified devices and the predicate devices.

Differences between the modified and the predicate EasyOne Pro Respiratory Analysis System devices:

- The modified devices differ in appearance from the predicate devices in that they have a different color scheme of the device housing, a different on/off button and a different design of the software user interface.
- A capacitive touch screen is used for the modified devices in comparison to the resistive touch screen used for the predicate devices.
- A different PC-board but providing the same functionalities is used for the modified devices.
- In the modified devices, a metal box around the CO or CO/CO_2 sensor provides improved EMC protection.
- A power supply of higher efficiency but identical environmental specifications is used for the modified devices.
- An internal USB stick instead of a CF card for internal back-up data storage is used for the modified devices.
- DISS gas hose connectors are used in the modified devices instead of the Quick Connectors used in the predicate devices.
- The board used for data acquisition is modified compared to the predicate device, but keeping the same functions.
- The outer geometry of the MMss sensor is modified compared to the predicate devices, but without modifying the operating principle and functionality of the sensor.
- For the modified EasyOne Pro LAB device model, a modified combined CO/CO_2 sensor is used; the modified combined CO/CO_2 sensor contains an additional reference path but has the same performance specifications as the combined CO/CO_2 sensor used in the predicate device.
- The modified devices use Windows 8 instead of Windows XP embedded operating system and SQLite/Microsoft SQL server as database technology instead of Microsoft Access.
- For the modified devices, some of the labelled specifications were updated to reflect the technical capabilities. No changes were made to the components the specifications relate to.

Design verification and validation demonstrated that the performance of the modified EasyOne Pro Respiratory Analysis System is the same as for the predicate EasyOne Pro Respiratory Analysis System. The modified as well as the predicate EasyOne Pro Respiratory Analysis System meet the ATS recommendations for accuracy and precision for spirometry, DLCO and MBW tests. The modified EasyOne Pro Respiratory Analysis System is therefore substantially equivalent to the predicate EasyOne Pro Respiratory Analysis System.

Summary of Testing:

Simulated Spirometry, DLCO and MBW testing, as well as testing with humans, confirmed that the modified EasyOne Pro Respiratory Analysis System devices meet the recommendations for accuracy and precision for Spirometry, DLCO and MBW tests of the American Thoracic Society (ATS).

The modified devices were tested to demonstrate conformance with the requirements for medical electrical equipment basic safety and essential performance of standards IEC 60601-1 and IEC 60601-1-2.

Software verification and validation in accordance with IEC 62304 confirmed that the modified EasyOne Pro Respiratory Analysis System meets the specified criteria.

Biocompatibility was evaluated in accordance with ISO 10993-1: Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process.

Conclusion:

Based on the above, ndd Medical Technologies concluded that the modified EasyOne Pro Respiratory Analysis System is substantially equivalent to the legally marketed predicate devices and is as safe and as effective for their intended use.