DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 5, 2017

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

Re: K161536
Trade/Device Name: EasyOne Air Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: May 31, 2016
Received: June 3, 2016

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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

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)*
K163536

Device Name
EasyOne Air Spirometer

Indications for Use *(Describe)*
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.

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

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<br>Technoparkstrasse 1<br>8005 Zurich, Switzerland |
| United states contact person: | Mr. Jerry Masiello<br>Operations Manager<br>ndd Medical Technologies, Inc |
| Phone: | (877) 904.0090 x11 |
| Fax: | (978) 824.3853 |
| Mailto: | jmasiello@nddmed.com |
| Date prepared: | May 31, 2016 |
| Submission type | Traditional 510(k) |

**Device name**:

| | |
|---|---|
| Proprietary name: | EasyOne Air Spirometer |
| Common name: | Spirometer |
| Classification name: | Diagnostic spirometer |
| Product code: | BZG |
| Regulation number: | 868.1840 |

**Predicate device:**

Substantial equivalence is claimed to the ndd EasyOne Spirometer, cleared for commercial distribution per K993921.

**Device Description:**

The ndd EasyOne Air is a diagnostic spirometer.

In order to conduct simple diagnostic spirometry testing, the EasyOne Air is used in combination with a commercially available disposable breathing tube with integrated mouthpiece (EasyOne Flow Tube).

The sensor is an ultrasound flow sensor that measures pulse transit-time to determine gas flow velocity and volume, as well as molar mass of the gas. The collected data is used for pulmonary function evaluation and data management. The results of the testing are stored in a database and reports can be displayed or printed.

**Intended Use:**

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 is used by general practitioners, specialists, and health care professionals, in hospitals and clinics, in pharmacies, and in clinical settings in occupational medicine.

The intended use, indications and patient population of the EasyOne Air Spirometer is similar to the predicate device EasyOne.

**Comparison of technological characteristics:**

The new device has the same technological characteristics with regards to spirometry testing as the predicate device, in particular the same sensor technology is used for spirometry testing. Both devices provide the same spirometry functions with the same test types, test parameters and utilize the same interpretation algorithms.

Differences between the EasyOne Air Spirometer and the predicate device: The new device has a larger, color, touch-enabled display in comparison to the predicate device which has a small, black/white display and a keyboard. The new device is capable of Bluetooth and wireless connectivity and uses a rechargeable battery pack in comparison to the standard batteries required for the predicate device. The new device also includes newly published clinical interpretation methods (GOLD(2008)/Hardie, Nice) compared to the predicate device.

The EasyOne Air device is used in combination with the disposable, single-use breathing tube ndd EasyOne Flow Tube. The predicate device is used in combination with the disposable, single-use breathing tube ndd Spirette.

The new ndd EasyOne Flow Tube has the same technological characteristics with regards to spirometry testing and patient hygiene concept as the ndd Spirette used in combination with the predicate device.

The patient-contacting part of the new breathing tube consists of poly(ethylene-co-propylene) in comparison to the predicate breathing tube, which consisted of polyethylene. Biocompatibility and cross-contamination prevention characteristics of the new breathing tube are the same as for the predicate breathing tube. The new breathing tube has a different shape (design) than the predicate breathing tube.

Design verification and validation demonstrates that the EasyOne Air spirometer used in combination with the EasyOne Flow Tube provides the same spirometry test results as the predicate device used in combination with the Spirette and is therefore substantially equivalent to the predicate device.

**Summary of testing:**

Dynamic wave form testing and comparative testing with a commercially available ndd Spirometer confirmed that the EasyOne Air Spirometer meets the spirometry recommendations for accuracy and precision published by the American Thoracic Society (ATS). Testing demonstrated equivalence to the predicate device with regards to performance of Forced Vital Capacity (FVC), Flow-volume loop (FVL), Slow Vital Capacity (SVC), and Maximal Voluntary Ventilation (MVV) spirometry test types.

The device was tested to demonstrate conformance with IEC 60601-1 and IEC 60601-1-2 requirements for electrical safety.

The materials used in the EasyOne Air device meet the requirements for biocompatibility in accordance with ISO 10993-1. Biocompatibility of the EasyOne Flow Tube was shown by testing for cytotoxicity (ISO 10993-5), sensitization and irritation (ISO 10993-10), chemical characterization (ISO 10993-18), particulate matter (ISO/FDIS 18562-2) and volatile organics (ISO/FDIS 18562-3).

Software verification and validation in accordance with IEC 62304 revealed that the EasyOne Air Spirometer meets the specified criteria.

Design Validation was successfully completed in accordance with IEC 62366.

**Conclusion:**

Based on the above, ndd Medical Technologies concluded that the EasyOne Air Spirometer is substantially equivalent to the legally marketed predicate device and is as safe and effective for its intended use.