SEP 27 2012

5 510(k) Summary K120635

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
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Date prepared:	February 22, 2012

Device Name:

Proprietary name:	EasyOne Pro Respiratory Analysis System
Common name:	Pulmonary function testing device
Class	Class II according to 868.1890
Classification name:	Calculator, Predicted Values, Pulmonary Function
Product code:	BTY

Predicate Device:

Substantial Equivalence is claimed with the SensorMedics Vmax 229 Series Pulmonary Function Analysis Instrument, K942211. The ndd Medical Technologies EasyOne Pro Respiratory System consists of two different device models: EasyOne Pro and EasyOne Pro LAB. The EasyOne Pro is currently marketed and cleared under K091428. The EasyOne Pro LAB is an enhanced version of the EasyOne Pro, which uses many of the technological characteristics implemented in the currently marketed EasyOne Pro. Both device models of the EasyOne Pro Respiratory Analysis System provide DLCO (Diffusion Capacity) tests including Lung Volume parameters and Spirometry tests. Compared to the EasyOne Pro the EasyOne Pro LAB includes measurement of the Functional Residual Capacity (FRC) based on the Multiple Breath Nitrogen (N2) Washout method.

Device Description:

The ndd EasyOne Pro Respiratory Analysis System is a portable device for performing lung function measurements. The device consists of a compact main unit and a hand-held sensor. Spirometry tests can be performed by connecting the hand-held sensor to the main unit. In order to perform DLCO and FRC tests a valve unit must additionally be connected to the hand-held sensor. The valve unit is connected with the main unit with a gas supply tube.
The spirette respiratory tube is a mouthpiece for single patient use, which is inserted in the sensor. In the valve unit there is also an accessory for single patient use inserted, which is called

barriette. The barriette prevents the passage of microorganisms into EasyOne Pro Respiratory Analysis System. A touch screen is integrated in the main unit that provides the user interface. The main power switch, different connections as well as different ports are located on the rear panel of the main unit. The EasyOne Pro can be used as a stand-alone system and can be connected to a network. The device has built-in quality control to assure correct test performance and equipment function.

Intended Use:

The ndd EasyOne Pro Respiratory Analysis System is designed for conducting lung function measurements in general or specialist practices or in hospitals. The EasyOne Pro Respiratory Analysis System can also be used outside of the laboratory when performing lung function screenings or measurements in occupational medicine. The EasyOne Pro Respiratory Analysis System 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 device has the same technological characteristics as the predicate devices. Testing was conducted to demonstrate that lung function measurements are as accurate and precise as the methods used in predicate devices. The new as well as the predicate devices meet the ATS recommendations for lung function measurements. The EasyOne Pro Respiratory Analysis System is therefore substantially equivalent to the predicate devices.

Summary of Testing:

Dynamic wave form testing was performed regarding the diagnostic spirometry tests. The DLCO performance was tested by using a DLCO simulator. In addition comparative measurements with another DLCO testing device demonstrate that the EasyOne Pro Respiratory Analysis System meets the ATS recommendations for accuracy and precision for DLCO testing and the intended diagnostic spirometry tests.

The multiple breath washout testing was performed using an FRC simulator. In addition to these in-vitro tests multiple breath washout tests in patients and healthy subjects were performed. Performance testing demonstrated that the acceptance criteria were successfully met.

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

The materials used meet the requirements for biocompatibility in accordance with ISO 10993.

Software verification and validation revealed that the EasyOne Pro Respiratory Analysis System meets the specified criteria.

Conclusion:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ndd Medizintechnik AG
C/O Mr. Gerard Masiello
Operations Manager
Ndd Medical Technologies, Incorporated
Two Dundee Park
Andover, Massachusetts 01810

SEP 27 2012

Re: K120635
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: September 12, 2012
Received: September 14, 2012

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: EasyOne Pro Respiratory Analysis System

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120635