

5 510(k) Summary

JUN - 2 2009

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
Mailto: jmasiello@nddmed.com
Date prepared: December 05, 2008

Device name:

Proprietary name: Easy on-PC Spirometer
Common name: Spirometer
Classification name: Diagnostic spirometer
Product code BZG

Predicate device:

Substantial equivalence is claimed to the Brentwood/Midmark Diagnostics IQmark Digital Spirometer, cleared for commercial distribution per K002499.

Device Description:

Easy on-PC is a PC based diagnostic spirometer and consists of a PC software and the Easy on-PC sensor (Spiroson-AS). The Easy on-PC software is installed on a Windows based PC or laptop computer to which the Easy on-PC sensor is connected.

In order to conduct simple diagnostic spirometry testing, the Easy on-PC sensor is used in combination with a commercially available disposable breathing tube with integrated mouthpiece (spirette).

The sensor is an ultrasound flow sensor that measures the transit-time to determine flow velocity, volume and molar mass of the gas. The collected data is transferred to the PC 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 Easy on-PC Spirometer is intended for prescriptions use only to conduct diagnostic spirometry testing of adults and pediatric patients over 4 years old, in general practice and specialty physician, industrial and hospital settings.

Comparison of technological characteristics:

The device has the same technological characteristics as the predicate devices except for the use of ultrasonic technology for flow measurement. Testing was conducted that demonstrates this method of flow measurement is as accurate as the methods used in predicate devices and therefore substantially equivalent to the predicate device.

Summary of testing:

Dynamic wave form testing confirmed that the Easy on-PC Spirometer meets recommendations published by the American Thoracic Society (ATS) for accuracy and precision for the intended diagnostic spirometry tests.

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 Easy on-PC software meets the specified criteria.

Conclusion:

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN - 2 2009

Re: K090034
Trade/Device Name: Easy on-PC Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: May 27, 2009
Received: May 28, 2009

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.

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/cdrh/comp/> 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Division 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: Easy on-PC Spirometer

Indications for Use:

The ndd Medical Technologies Easy on-PC Spirometer is intended for prescriptions use only to conduct diagnostic spirometry testing of adults and pediatric patients over 4 years old, in general practice and specialty physician, industrial and hospital settings.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090034