MAY 2 3 2000

K993921

510(k) SUMMARY

ndd Medical Technologies

ndd Medical Technologies EasyOne™ Spirometer

November 17, 1999

Submitter Information:

Submitter's Name:	ndd Medical Technologies 17 Progress Avenue Chelmsford, MA 01824
Telephone:	(978) 244-0620

Device Name:

Proprietary name:	ndd Medical Technologies EasyOne™ Spirometer
Common Name:	Spirometer
Classification Name:	Diagnostic spirometer

Predicate Device Equivalence:

Substantial equivalence is claimed to the Puritan-Bennett Renaissance Spirometer, cleared for commercial distribution per K944672, and other legally marketed devices.

Device Description:

The ndd EasyOne™ Spirometer system consists of the following:
EasyOne™ Spirometer (either the Frontline Model 2000 or the Diagnostic Model 2001)
Disposable Spirette
Cal coupler (used to connect the spirometer to the calibration syringe)
EasyStart User Instructions
EasyGuide Technical Information
EasyOne™ Cradle (optional)
Printer cable (optional)
Two AA alkaline batteries

Intended Use:

The ndd Medical Technologies EasyOne™ Spirometer is intended for prescription use only to conduct simple 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 devices.

Summary of Testing:

Performance testing was conducted to demonstrate compliance with the hardware and software requirements defined in the EasyOne™ Spirometer Requirements Specification, including requirements for accuracy defined by the American Thoracic Society.

The device was tested to demonstrate conformance to the applicable requirements contained in Section (h) (1) – (7) and Section (i) of Appendix A of the November 1993 Draft document "Reviewer Guidance for Premarket Notification Submissions".

The device was tested to demonstrate conformance with IEC601-1 requirements for electrical safety.

Biocompatibility testing was conducted in accordance with Office of Device Evaluation General Program Memorandum #G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."

Conclusions:

Based on the above, we concluded that the ndd Medical Technologies EasyOne™ Spirometer is substantially equivalent to 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
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2000

Mr. Oscar Kaelin
CEO
ndd Medical Technologies
17 Progress Avenue
Chelmsford, MA 01824

Re: K993921
EasyOne™ Spirometer
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: March 10, 2000
Received: March 14, 2000

Dear Mr. Kaelin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name:

ndd Medical Technologies EasyOne™ Spirometer

Indications for Use:

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for

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993921