APR 30 1998

K980411

Section 16. 510(k) Summary

Section 16.a Date Summary Prepared

30 January 1998

Section 16.b Company Information

Establishment:

Nellcor Puritan Bennett Inc.
4280 Hacienda Drive
Pleasanton, CA 94588

Official Correspondent:

David A.C. Green
Manager, Regulatory Affairs
Nellcor Puritan Bennett Inc.
11150 Thompson Avenue
Lenexa, KS 66219
(913) 495-7140 (direct phone)
(913) 495-7285 (fax)

Section 16.c Name of Device

Proprietary:	NPB-500 Spirometry System
Common/Usual:	Spirometer
Classification:	Spirometer (§868.1840/73BZG)

Section 16.d Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for the predicate devices and the NPB-500 Spirometry System. Safety and environmental testing to accepted industry standards has been conducted as well as in-vitro testing to confirm the accuracy of the NPB-500 Spirometry System. The predicate devices are as follows:

1. Nellcor Puritan Bennett Inc., NPB-Renaissance Spirometer, K944762
2. Vitalograph Ltd., Model 2120 Spirometer, K946075

Section 16.e Device Description

The NPB-500 Spirometry System comprises the following five components, including accessories: NPB-500 Spirometer (hand held), Flow Sensor II, Pressure Tubing, NPB-510 Spirometer Base (optional) and Printer/PC Cable (optional}. Two versions of the cable are available, namely, a parallel cable for a Printer and a serial cable for a PC.

The NPB-500 is a hand held diagnostic Spirometer intended for patient use in the performance of Forced Vital Capacity, FVC, testing. The patient performing a test is requested to take a deep breath and then exhale vigorously and continuously into the sensor's mouthpiece until complete exhalation is achieved. Initially, the testing process requires patient cooperation and supervisory coaching to achieve optimum results.

FVC parameter test results may be displayed on the Spirometer's front face LCD display. Alternatively, the Spirometer can be inserted into the optional Spirometer Base, enabling data to be interfaced, via an output data port, to a parallel printer for graphical printout of the patient's test record, or to a PC.

In addition to the above mentioned device features, the instrument has been designed to satisfy the needs of both the user and the patient. An audible, mid frequency, beep tone is provided to prompt the User for input, inform the User of the successful completion of a process step or warn of low battery condition. The NPB-500 System is powered by two AA size standard alkaline batteries which can provide an estimated operating time of six months under normal use.

Section 16.f Intended Use

The **NPB-500 Spirometry System** is intended for prescription use only to conduct simple diagnostic forced vital capacity (FVC) testing of adults plus pediatric patients, in the patient examination rooms of a physician's practice and in hospital or hospital-type facilities such as respiratory care centers. The intended use, patient population and environment of use are the **same or similar** to the predicate devices, the NPB-Renaissance Spirometer and the Vitalograph model 2120 Spirometer.

Section 16.g Technological Characteristics

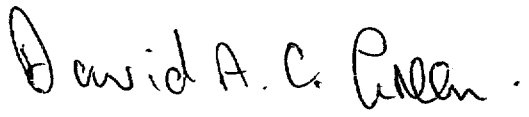
A pneumotachometer sensor is used to convert the expired breath flow signal into a pressure signal. The NPB-500 Spirometry System measures the values of FVC parameters by continuously sensing this pressure throughout an expired breath. This signal is pneumatically coupled to a pressure transducer in the NPB-500 Spirometer to develop corresponding electrical data. Conventional electronics and embedded software are used to process this data and generate numerical values of FVC parameters for presentation on the NPB-500's LCD display. Alternatively, graphical test results may be recorded on a printer.

The embedded software contains **substantially the same software algorithm** for determining test values of FVC parameters as used on the predicate device, the NPB-Renaissance, cleared under K944762, except for the inclusion of non-linear correction terms in the pressure/flow equation of the sensor.

Section 16.h Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Nellcor Puritan Bennett Inc. believes that all data and information submitted in this Premarket Notification are truthful and accurate and no material fact has been omitted.



David A. C. Green
Manager, Regulatory Affairs
for Nellcor Puritan Bennett Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

Mr. David A.C. Green
Nellcor Puritan Bennett Inc.
11150 Thompson Avenue
Lenexa, KS 66219-2301

Re: K980441
NPB-500 Spirometry System
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: February 3, 1998
Received: February 4, 1998

Dear Mr. Green:

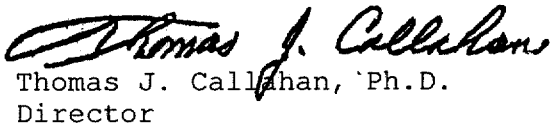
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980441

Device Name: NPB-500 Spirometry System

Indications For Use:

The **NPB-500 Spirometry System's** intended use is simple diagnostic forced vital capacity (FVC) testing for adults of all ages plus pediatric patients, in the patient examination rooms of a physician's practice and in hospital or hospital-type facilities such as respiratory care centers. The NPB 500 Spirometry System is for prescription use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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