K023225

PURITAN-BENNETT

4280 Hacienda Drive
Pleasanton, CA 94588

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DEC 1 8 2002

510(k) Summary

Submitted by:

Puritan-Bennett Corporation
2200 Faraday Avenue
Carlsbad, CA 92008

Company Contact:

Gina To
Senior Regulatory Affairs Project Manager
Nellcor Puritan Bennett, Inc.
4280 Hacienda Drive
Pleasanton, CA 94588
(925) 463-4427
(925) 463-4020 – FAX

Date Summary Prepared:

December 10, 2002

Trade Name:

Puritan Bennett DataFlow™ Data Management Software

Common/Usual Name:

Diagnostic Spirometer

Classification Name:

Spirometer, Diagnostic
(BZG) per 21 CFR §868.1840

Legally Marketed Predicate Device:

Puritan-Bennett Renaissance Spirometry System with the Optional Renaissance DB Data Management Software, 510(k) #K944762

Device Description

Puritan Bennett DataFlow™ Data Management Software is a software program used in conjunction with the Puritan Bennett PB-700 Renaissance® II Spirometer System and the Nellcor Puritan Bennett NPB-500 Simplicity™ Spirometer System to transfer patient test data from the spirometer to an IBM compatible Personal Computer. Once transferred, the DataFlow software allows the operator to perform any or all of the following: edit or add patient demographic information, archive the test, search for and retrieve archived test(s), print test reports, compare archived tests, and export test data for use by other application software.

Intended Use

The DataFlow software program is intended to augment the data management capability of the Puritan Bennett PB-700 Renaissance® II Spirometer System and the Nellcor Puritan Bennett NPB-500 Simplicity™ Spirometer System. The DataFlow software program is for use by healthcare professionals (e.g., technicians, nurses and/or physicians) in hospitals, physicians' offices, alternate care and occupational health environments under the direction of a physician. DataFlow is not intended for use by patients.

Summary of Technological Characteristics of the Device Compared to the Legally Marketed Device

The Puritan Bennett DataFlow™ Data Management Software has the same technological characteristics as the above referenced predicate device. The intended use of the DataFlow software is the same as the predicate device inasmuch as the function of DataFlow is to augment the spirometer's data management capability. The DataFlow software has the same technological characteristics as the predicate device, where both are PC-based standalone software programs and offer similar basic features.

Tests Performed to Support Determination of Substantial Equivalence

The performance of the DataFlow software program was comprehensively tested with the PB-700 and NPB-500 spirometers. All functions as defined in the specifications were completely verified and validated.

DataFlow adheres to the following FDA CDRH guidances:

- CDRH *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, May 29, 1998
- CDRH *Off-The-Shelf Software Use in Medical Devices*, September 9, 1999

Conclusions

The DataFlow software program performs as intended according to its performance specification. DataFlow is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

Ms. Gina To
Senior Regulatory Affairs Project Manager
Puritan Bennett Corporation
4280 Hacienda Drive
Pleasanton, California 94588-2719

Re: K023225
Trade Name: Puritan Bennett DataFlow™ Data Management Software
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: 73 BZG
Dated: September 26, 2002
Received: September 27, 2002

Dear Ms. To:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023225

Device Name: Puritan Bennett DataFlow™ Data Management Software

Indications For Use:

The Puritan Bennett DataFlow™ Data Management Software is intended to augment the Puritan Bennett PB-700 Renaissance® II Spirometer System and the Nellcor Puritan Bennett NPB-500 Simplicity™ Spirometer System's data management capability.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription Use -OR- _ Over-the-counter Use

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

510(k) Number K023225