K022103

SEP 27 2002

510(k) Summary

Submitted by:	Puritan Bennett Incorporated 2200 Faraday Avenue Carlsbad, CA 92008
Company Contact:	James R. Bonds Senior Director, Regulatory and Clinical Affairs (925) 463-4371 (925) 463-4020 - FAX
Date Summary Prepared:	June 28, 2002
Trade Name:	PB700 Renaissance II Spirometry System
Common/Usual Name:	Diagnostic Spirometer
Classification Name:	Spirometer, Diagnostic per 21 CFR §868.1840
Product Code:	BZG
Legally Marketed Predicate Device (Unmodified):	PB100 Renaissance Spirometry System, K944762

Device Description

The PB700 Spirometry System consists of the Renaissance II Spirometer, the PB710 Base Station, AC Adapter, the disposable FSII Flow Sensor, a syringe adapter (for calibration), and nose clips. Optional accessories include calibration syringe, printer and serial communications cables, and a compatible printer. The Renaissance II Spirometry System is designed for use in the diagnosis, assessment, and monitoring of certain lung diseases.

Intended Use

The Renaissance II Spirometry System is a diagnostic tool used to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. This testing can be used in the detection and monitoring of certain lung diseases. The system is intended for use with pediatric and adult patients (4 to 99 years) in hospitals, physicians' offices, laboratories, and occupational health testing environments.

Summary of Substantial Equivalence

The Renaissance II Spirometry System has the same technological characteristics as the above referenced predicate device. In both devices, air flow is directly measured via a sensor and connecting pressure tube, then electronically integrated to obtain volume. Both the modified and unmodified devices then perform calculations to express the volume in clinically relevant terms, including comparisons to predicted normal values from published literature. The intended use of the modified and predicate device is the same.

The modified PB700 Renaissance II Spirometry System has been tested and found to meet all design criteria. The modifications to the predicate device have been carried out with appropriate design control procedures.

Conclusion

The modified PB700 Renaissance II Spirometry System does not raise new questions of safety or effectiveness when compared to the legally marketed predicate device, and the modified device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2002

Mr. James Bonds
Senior Director, Regulatory Affairs
Puritan-Bennett Corporation
2200 Faraday Avenue
Carlsbad, California 92008

Re: K022103
Trade/Device Name: PB700 Renaissance II Spirometry System
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: September 6, 2002
Received: September 9, 2002

Dear Mr. Bonds

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

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): K022103

Device Name: PB700 Renaissance II Spirometry System

Indications For Use:

The PB700 Renaissance II Spirometry System is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician's offices, laboratories, and occupational health testing environments.

(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: K022103

Prescription Use ✓ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)