K123896

Section 5

510(k) Summary

SUBMITTER INFORMATION

Benson Medical Instruments Company
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Minneapolis, MN 55415

CONTACT PERSON

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SEP 10 2013

DATE PREPARED

September 5, 2013

DEVICE NAME

Proprietary Name:	CCS-200 Spirometer
Common Name:	Spirometer
Classification Name:	Diagnostic Spirometer (21 CFR 868.1840)
Product Code:	BZG

PREDICATE DEVICES

The CCS-200 Spirometer is substantially equivalent to the ndd Medical Technologies **Easy on-PC** Spirometer per 510(k) number K090034 and the ndd Medical Technologies **EasyOne** Spirometer per 510(k) number K993921.

DEVICE DESCRIPTION

The CCS-200 Spirometer System consists of Microsoft Windows based personal computer (PC) software (BUL) and the CCS-200 flow sensing instrument. The BUL software is installed on a desktop or laptop PC to which the CCS-200 flow sensing instrument is connected.

In order to conduct spirometry testing the CCS-200 flow sensing instrument is used in combination with a single-use disposable airway tube with integrated mouthpiece (U-tube).

The flow sensing instrument measures transit time of ultrasound pulses through the air in the U-tube to determine flow velocity and volume. The collected data are transferred to the PC for pulmonary function evaluation and data management. The results of the testing are stored in a database. Reports can be displayed or printed.

INTENDED USE

The CCS-200 Spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients who are at least 16 years old, in general practice, specialty physician, industrial and hospital settings.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The CCS-200 Spirometer has similar technological characteristics to the predicate devices.

Both use single-use mouthpieces. These vary in dimensions and materials used. Bench testing to ATS standards and biocompatibility testing ensure that the differences do not result in testing errors or human reactions.

Both use ultra-sonic transducers to measure airflow with time of flight calculations in firmware. While the specific algorithms may vary, bench testing to ATS standards ensure test validity.

The CCS-200 contains a subset of testing indices and predicted normal sets, as the additional ones are not required for the occupational health market in the United States.

SUMMARY OF TESTING

Dynamic wave-form testing confirmed that the CCS-200 Spirometer meets recommendations published by the American Thoracic Society (ATS) for accuracy and precision for the intended diagnostic spirometry functions. American Thoracic Society. 1995. "Standardization of Spirometry: 1994 Update." American Journal of Respiratory and Critical Care Medicine 152: 1107–1136 provides standardized waveforms with defined values of the indices FVC, FEV1, FEF25-75, and PEF. These waveforms were performed with the CCS-200 spriometer using a mechanical device known as a flow-volume simulator (FVS) and results were compared to the acceptance criteria as well as to results obtained from a predicate device with the same FVS. In addition, human testing with both the CCS-200 and predicate device were compared. All results were within the defined ATS acceptance criteria.

The device was tested to demonstrate conformance with IEC 60601-1 and IEC 60601-1-2 requirements for electrical safety and electromagnetic compatibility.

The device and U-tube airway/mouthpiece were tested to demonstrate conformance with the requirements for biocompatibility in accordance with ISO 10993 with tests indicate from Table 1 of FDA memorandum #G95-1. The single-use mouthpiece contacts both skin and mucosal membranes for limited duration of less than 24 hours. These components were tested for cytotoxicity,

sensitization, and intracutaneous reactivity. The case components, comprising the left and right halves, label material, release button, U-channel, and ejection pin, contacts the skin for limited duration of less than 24 hours, and was tested for cytotoxicity, sensitization, and intracutaneous reactivity. The actual tests performed on all components were MEM elution and neutral red uptake (cytotoxicity per ISO 10993-5 2009), intracutaneous injection (intracutaneous reactivity per ISO 10993-10 2010), and Kligman maximization (sensitization per ISO 10993-10 2010). All tests results met the requirements of the ISO standard for biocompatibility.

Software verification and validation testing indicates that the CCS-200 software meets the specified criteria.

CONCLUSION

Based on the work summarized above, we concluded that the Benson Medical Instruments Company CCS-200 Spirometer is substantially equivalent to the legally marketed predicate devices and is at least as safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 10, 2013

Benson Medical Instruments Company
Mr. David P. Mayou
Quality Manager
310 4th Avenue South, Suite 5000
MINNEAPOLIS, MN 55415

Re: K123896
Trade/Device Name: CCS-200 Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: August 12, 2013
Received: August 13, 2013

Dear Mr. Mayou:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

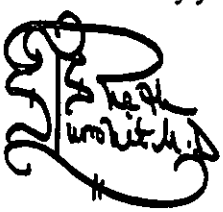
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Tejashri Purohit-Sheth, M.D.
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FOR

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Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K123896

Device Name: CCS-200 spirometer

Indications For Use:

The CCS-200 Spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients who are at least 16 years old, in general practice, specialty physician, industrial, and hospital settings.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.09.09 14:17:11 -04'00'