K130322 NOV 15 2013

1. 510(k) Summary - Basic Information

1.1 Submitter

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Date Prepared: March 26, 2013

1.2 Device Name

Device Name:	SPM-300
Common Name:	Spirometer
Classification Name:	Diagnostic Spirometer (868.1840, Class II)
510(k) Number	K130322

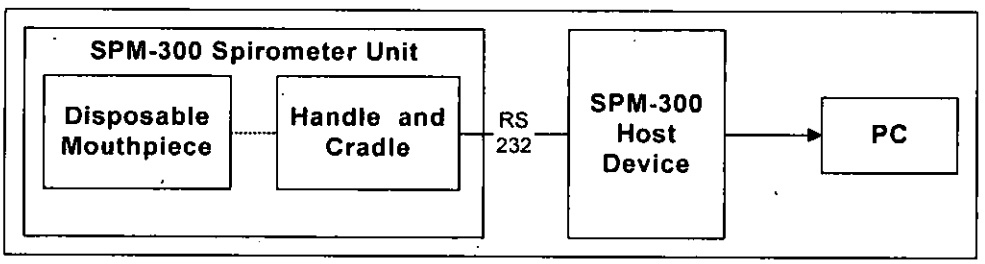
1.3 Identification of Legally Marketed Device

Substantial equivalence is claimed to the Caird Technology Spirometer (K971336), which is marketed as the Medikro spirometer.

1.4 Device Description

SPM-300 is a pulmonary function monitoring system consisting of a spirometry data acquisition unit (spirometer handle and mouthpiece) and a host device that provides data analysis and management, display and user interface functions. (See Figure 1).

Figure 1: SPM-300/Host Block Diagram



1.5 Intended Use

SPM-300 is intended for use as a diagnostic tool by trained operators in healthcare facilities. It provides the following functions:

- Acquire pulmonary function data.
- Input patient data.
- Use Host device to
  - View, store and print captured data.
  - Analyze captured data; display and print analysis results.
  - Retain captured data and analysis results for up to 120 patients.

- Transfer retained data to a PC.

1.6 Indications for Use

The SPM-300 Spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients in general practice, specialty physician, and hospital settings.

1.7 Comparison to Cleared Device

Bionet believes that SPM-300 is substantially equivalent to the Caird Technology Spirometer (K971336) with respect to essential characteristics, user interface, and measurement characteristics. This device is marketed as the Medikro spirometer and was selected as the predicate for SPM-300 because both can be used in conjunction with EKG measurement devices that provide all user interface functions. Table 1 compares SPM-300 to the Medikro spirometer for the several characteristic specified above.

1.7.1 Comparison of Indications for Use to Recently Cleared Device

SPM-300's Indications for Use derive from the spirometer most recently cleared by FDA, which is Benson Medical Instruments' CCS-200 Spirometer (K123896).

Table 1: Comparison of SPM-300 to Predicate Device

	Bionet SPM-300 Spirometer	Medikro D9 Spirometer
Essential Characteristics		
Device Type	Diagnostic Spirometer	same
Target Population	Adult and pediatric patients	same
Where used	Healthcare facilities	same
Indication for Use	The SPM-300 Spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients in general practice, specialty physician, and hospital settings.	See 1.7.1.
Mouthpiece	Disposable	same
Environment	• Temperature: 15 ~ 40° C (59 ~ 104° F) • Relative humidity: 10 to 90% (non-condensing) • Atmospheric pressure: 700 to 1060hPa	• Temperature: 10 ~ 40°C (50 ~104 °F) • Relative humidity: 15 ~ 95% (non-condensing) • Atmospheric pressure: 700 ~ 1060 hPa
Power supply	AC or optional built-in battery 95~240 VAC, 50/60Hz, 1.0~0.5A, 60W max	Universal AC Power supply (100~240 VAC at 50/60Hz) 65 VA
User Interface Comparisons		
User Interface	Provided by Host Device (Cardio7 or CardioTouch3000)	Provided by external device
Presentation	• Volume/time curve • Flow/volume curve • Measurement Values Table	• Volume/time curve • Flow/volume curve • Tidal volume • Both volume/time and displayed curves • No curves
Data storage	Up to 120 tests	Up to 50 tests
Measurement Comparisons		
Measured values	• FVC: FVC, FEV1, FEV1/FVC, FEF 0.2-1.2L, FEF 25-75%, FEF 75-85%, PEF, FEF 25%, FEF 50%, FEF 75%, • SVC: SVC, ERV, IRV, TV, EC, IC, RV • MVV: MVV, FB, TV	• FVC: FVC, FIVC, FIV1, FIV1%, FEV0.5, FEV1, FEV2, FEV3, FEV5, FEV6, FEV1/FEV6, FEV0.5%, EV1%, FEV2%, FEV3%, FEV5%, FEV6%, PEF, FEF25, FEF50, FEF75, FEF0.2-1.2, FEF25-75, FEF75-85, PIF, FIF50, FEF50/FIF50, FET • SVC: SVC, ERV, IRV, VT, IC, BF, MV, Tin, Tex, Tin/Tex

	Bionet SPM-300 Spirometer	Medikro D9 Spirometer
Measurement range	• Flow: 0 to ±14 L/s • Volume: 0 to ±11 L	• Flow: 0 to 14 L/s • Volume: 0 to 11 L
Measurement method	Differential pressure method	Pneumotach
Prediction equation	Morris-Polgar, ECCS-Quanjer, Knudson-ITS	Berglund, Crapo, ECCS/Quanjer, Falaschetti, Forche II, Gore, Gulsvik, Hedenström, Knudson, Kory, Morris, NHANES III, Paoletti, Roca, Schoenberg, Viljanen
Measuring accuracy	Complies with ATS (American Thoracic Society) standards.	same

1.7.2 Differences between SPM-300 and Medikro Spirometer

There are no meaningful differences between the Essential Characteristics of SPM-300 and the Medikro Spirometer with respect to safety or efficacy. The temperature and humidity ranges are slightly different but both devices can be used in the same environments and these slight differences do not affect performance of the spirometry function. There are minor power supply differences, but both power supplies adequately cover the US power environment.

The differences in the User Interface and Measurement categories do not make SPM-300 less safe or less effective than the Medikro Spirometer as described in the following paragraphs.

1.7.2.1 User Interface Difference

The only User Interface difference is the presentation of pulmonary test data. This difference in presentation does not make SPM-300 less safe or less effective than the Medikro Spirometer because both devices display the same curves and parameters.[1]

- Both use external devices to display graph and parameter data.
- Both display Volume/time curve and Flow/volume curve.
- The predicate displays standalone Tidal volume but SPM-300 displays Tidal volume in its Measurement Values Table (along with other parameters).

1.7.2.2 Measurement Differences

The measurement accuracy of both devices is assured by compliance with ATS standards. The several measurement differences do not make SPM-300 less safe or less effective than the Medikro Spirometer because the SPM-300 algorithm calculates the same parameters as the predicate device but only shows the important parameters to reduce complexity.

Even though their measurement methods differ, both devices ultimately derive lung volume from air flow.

- The predicate device uses the pneumotachometer sensor to measure air flow directly.
- SMP-300 uses a symmetric pivot tube to get the differential air pressure which it uses to derive air flow using Bernoulli's principal.

[1] The difference in data storage capacities does not affect the actual performance of spirometry.

The different measurement methods do not affect spirometry performance because the accuracy of air flow measurement for both devices is within the ATS tolerance.

The popular prediction equation in the US is the Morris-Polgar equation, which both devices provide. While the predicate provides more prediction equations than SPM-300, the difference is choice rather than performance.

1.8 Biocompatibility

The patient contact component of the SPM-300 Spirometer is the SmarTube™ disposable mouthpiece, which is inside the patient's mouth during spirometry testing. Bionet contracted an independent testing organization to conduct the following biocompatibility testing for the mouthpiece in accordance with the ISO 10993 standard:

- cytotoxicity
- skin sensitization
- oral mucosa irritation

The independent testing organization found (and certified) that the disposable mouthpiece meets or exceeds all biocompatibility requirements for components with patient contact duration $\leq$ 24 hours in accordance with the ISO 10993 standard.

2. Performance Information

SPM-300 has been demonstrated to comply with the ATS (American Thoracic Society) standards for measuring FVC, FEV1, MVV, and PEF (accuracy and repeatability). This is based on the recommendation of the ATS/ERS Task Force titled, "Standardisation of Lung Function Testing; Standardisation of spirometry".

SPM-300 was subjected to Electrical Safety and EMI (Electromagnetic Interference) testing in accordance with the IEC 60601 standard (Part 1: General requirements for safety and Part 1-2, Electromagnetic Compatibility Requirement and tests). SPM-300 was found to satisfy the requirements of both parts of the standard.

The patient contacting component of SPM-300 (disposable mouthpiece) was subjected to biocompatibility testing as described in 1.8 (above).

3. Conclusion.

Based on non-clinical testing, SPM-300 has been demonstrated to be as safe and as effective as the Caird Technology Spirometer predicate device (K971336).

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

November 15, 2013

Bionet Company, Limited
C/O Marc Goodman, Senior Associate
Noblitt & Rueland
5405 Alton Parkway 5A, Suite A530
IRVINE, CA 92604

Re: K130322
Trade/Device Name: SPM-300
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: September 27, 2013
Received: October 7, 2013

Dear Mr. Goodman:

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.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130322

Device Name
SPM-300

Indications for Use *(Describe)*
The SPM-300 Spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients in general practice, specialty physician, and hospital settings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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: 2013.11.15 15:48:05 -05'00'