DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2015

Medikro Oy
Mr. Mikko Eloranta
Managing Director
Kellolahdentie 27
FI-70460 Kuopio
Finland

Re: K120577
Trade/Device Name: Medikro SpiroStar USB and Medikro SpiroStar DX
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: June 15, 2015
Received: June 18, 2015

Dear Mr. Eloranta:

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 Industry and Consumer Education 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 Industry and Consumer Education 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
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Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120577

Device Name: Medikro® SpiroStar

Models: M929, Medikro SpiroStar USB and M921, Medikro SpiroStar DX

Indications For Use:

Medikro Spirometer is a device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values.

The device is designed for

- adult and pediatric patients,
- hospital and clinic use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

General Information

Date:	24.6.2015
Trade Names**:**	M929, Medikro SpiroStar USB and M921, Medikro SpiroStar DX
Common Name:	Diagnostic Spirometer
Classification Name:	Spirometer, Diagnostic
Classification:	Class II
Manufacturer:	Medikro Oy Pioneerinkatu 3 FI-70800 Kuopio Finland tel: +358 17 283 3000
Corresponding Official:	Mikko Eloranta, Managing Director tel: +358 17 283 3000 fax: +358 17 283 3300
Predicate Devices:	Caird Technology Spirometer, K971336 Welch Allyn CardioPerfect Workstation, Software Version 1.5.0, K052158

Device Description

Medikro® SpiroStar spirometer runs on a personal computer with Microsoft Windows operating systems.

Medikro® SpiroStar spirometer unit is connected to PC via USB port (USB model) or via serial port (DX model). SpiroSafe disposable flow transducer is connected to the spirometer unit via pressure tube. A nose clip is used to prevent air flow from nose during measurements. Optional calibration syringe is used for recommended daily volume calibrations.

Medikro® SpiroStar spirometers are used to measure lung air volume and airflow rate. Medikro® Spirometry Software is used to perform the measurement and calculate the measurement volume based on chosen reference value. The reference value is based on patient's gender, race and age. User can analyze the results in different presentations and create a final report based on the results and patient information.

The spirometers take all the power that it needs from the USB or serial port, so no other external or internal power supply is needed.

Indications for Use

Medikro Spirometer is a device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values.

The device is designed for

- adult and pediatric patients,
- hospital and clinic use only.

Nonclinical tests

Following tests were made to the devices:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)). (General)
- IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1. (General)
- American Thoracic Society and European Respiratory Society (Eur Respir J, 2005, Vol 26, pp. 948-968. No. 5 in SERIES ‘‘ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING’’)

Conclusion for Nonclinical tests

Complete IEC 60601-1 testing was carried out for the equipment. Full test reports were made for both M929 Medikro® SpiroStar USB and M921 Medikro® SpiroStar DX (Serial). The equipment was found to comply with standard requirements.

IEC 60601-1-2 EMC testing was made for both sensor units (USB and DX). EMC testing was made according to IEC/EN 60601-1-2 requirements and includes both emissions and immunity testing. Testing was performed at Savonia Polytechnic EMC laboratory by the laboratory test engineer. Full test reports were made for both M929, Medikro® SpiroStar USB and M921, Medikro® SpiroStar DX (Serial).

IEC 60601-1-4 testing was made and the equipment was found to comply with standard requirements.

American Thoracic Society (ATS) 24 standard waveforms test was made for both units (USB and DX) and both units meet the recommendations for:

- Measuring FVC
- Measuring FEV1
- Measuring FEF25-75%
- Measuring PEF
- Resistance to flow
- Testing under BTPS conditions

Testing was done for the Medikro Oy measurement devices against recommendations published by the American Thoracic Society. The essential performance criteria's for spirometers is well defined by the ATS. Spirometers meeting ATS criteria for essential performance are substantially equal. The predicate devices are also designed to meet these ATS criteria.

Key Technological Characteristics

Feature	Predicate Device 510(K) Number K971336	Predicate Device 510(K) Number K052158	New Device Medikro® SpiroStar
Device classification	**Spirometer, diagnostics**	**Spirometer, diagnostics**	**Spirometer, diagnostics**
Target population	**Adult and pediatric patients**	**Adult and pediatric patients**	**Adult and pediatric patients**
Use environment	**Hospital/Clinical**	**Hospital/Clinical**	**Hospital/Clinical**
Indices measured	**FEV1, FVC, FEV1/FVC, PEF, FEF25-75% +others**	**FEV1, FVC, FEV1/FVC, PEF, FEF25-75% +others**	**FEV1, FVC, FEV1/FVC, PEF, FEF25-75% +others**
Real-time display of each blow	**Yes**	**Yes**	**Yes**
Feedback about test quality	**Yes**	**Yes**	**Yes**
Flow-volume displayed & printed	**Yes**	**Yes**	**Yes**
Volume-time printed	**Yes**	**Yes**	**Yes**
Quantifies post bronchodilator change	**Yes**	**Yes**	**Yes**
Prints predicted flow-volume curve	**Yes**	**Yes**	**Yes**

Feature	Predicate Device 510(K) Number K971336	Predicate Device 510(K) Number K052158	New Device Medikro® SpiroStar
Includes interpretation software	**Yes**	**Yes**	**Yes**
Results download to clinical software	**Yes**	**Yes**	**Yes**
Patient result storage capacity	**Depending the size of the data storage media**	**Depending the size of the data storage media**	**Depending the size of the data storage media**
Portable/not portable	**Portable with laptop PC**	**Portable with laptop PC**	**Portable with mobile PC**
Power source and connection to PC	**PC Serial connection**	**PC USB or Serial connection**	**PC USB or Serial connection**
ATS compatible	**Yes**	**Yes**	**Yes**
Flow Transducer	**Disposable**	**Disposable**	**Disposable**

The New Device has the same intended use and safety characteristics as the predicate devices.

Conclusion

Based on completed performance testing our device demonstrates that it is substantially equivalent to the predicate device.