DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 3, 2014

Beijing M&B Electronic Instruments, Co., Ltd.
C/O Mr. Mike Gu
Regulatory Affairs Manager
Osmunda Medical Device Consulting Co., Ltd
7th Floor, Jingui Business Building, No. 982 Congyun Rd
Baiyun District
Guangzhou, Guangdong
China 510420

Re: K133975
Trade/Device Name: MSA100 Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Meter, Peak Flow, Spirometry
Regulatory Class: II
Product Code: BZH
Dated: August 20, 2014
Received: August 22, 2014

Dear Mr. Gu:

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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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133975

Device Name
MSA100 Peak Flow Meter

Indications for Use *(Describe)*
This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient home use. The device is designed for pediatric to adult patients. The device is intended for monitoring respiratory conditions such as asthma.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	20 Dec 2013
Submitter:	Beijing M&B Electronic Instruments Co., Ltd, Room 6319, Building 1, No. 27, Yongwang Road, Beijing Bioengineering and Medicine Industry Base, Huangcun Town, Daxing district, Beijing, People's Republic of China
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Secondary Contact Person:	Mike Gu Regulatory Affairs Manager OSMUNDA Medical Device Service Group Tel: +86-20-62321333 Fax: +86-20-86330253
Device: Trade Name:	MSA100 Peak Flow Meter
Common/Usual Name:	Peak Flow Meter
Regulation number	868.1860
Classification Names:	Meter, Peak Flow, Spirometry
Product Code:	BZH
Predicate Device(s):	K040723, MICROLIFE ELECTRONIC PEAK FLOW MONITOR, WITH PEF AND FEV1, MODELS PF-100 AND PF-100-1 (WITH SOFTWARE)
Device Description:	The MSA100 Peak Flow Meter is a medical device that measures patient's maximum possible exhalation which is called "peak flow" (referred to in medical terms as PEF-Peak Expiratory Flow) and "forced expiratory volume" (commonly known as FEV1) in one second. Regular monitoring of the peak flow is useful for monitoring diseases of the airways such as asthma, C.O.P.D, or chronic bronchitis, is usually used for patient home use.
Intended Use:	This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient home use. The device is designed for pediatric to adult patients. The device is intended for monitoring respiratory conditions such as asthma.

Technology:

Technically, the turbine transducer is the key component for both predicate and proposed device, when air flow passes through, it makes the leaf of turbine rotate. Rotary speed of the leaf is linear relationship with air flow rate. By the technology of photoelectric conversion, turning of the leaf is converted to be pulse signal, which is processed by the main controller after sampling.

Specification	**Predicate Device** **Microlife Electronic Peak Flow Monitor**	**Proposed** **MSA100 Peak Flow Meter**
Device name	Microlife Electronic Peak Flow Monitor, with PEF and FEV1, Models PF-100 and PF 100-1	MSA100 Peak Flow Meter
Manufacturer	Microlife Intellectual Property GmbH	Beijing M&B Electronic Instruments Co., Ltd
Patient Population	The device is designed for pediatric to adult patients	The device is designed for pediatric to adult patients
Environment of Use	OTC	OTC
Measuring range	PEF from 50 to 900 l/min FEV1 from 0.01 to 9.99 liters	PEF from 50 to 900 l/min FEV1 from 0.01 to 9.99 liters
Measuring method	Flow: Turbine sensor Volume: Flow Integration	Flow: Turbine sensor Volume: Flow Integration
Accuracy	PEF ± 25 l/min or 12% of the reading; FEV1 ± 0.1 l or ± 5% of the reading	PEF ± 20 l/min or± 10% of the reading; FEV1 ± 0.05 l or ± 3% of the reading
Measuring solution	PEF 1 l/min; FEV1 0.01 l	PEF 1 l/min; FEV1 0.01 l
Data safety	Data rememorized by EEPROM	Data rememorized by Flash memory
Memory	240 measurements with date/time	300 measurements with date/time
Power source	2 batteries of 1.5V, size AAA	AAA 1.5×2 alkaline batteries

Electrical Safety	IEC 60601-1 and IEC 60601-1-2	IEC 60601-1 and IEC 60601-1-2

The following technological differences exist between the proposed device and the predicate device:

- Use of flash memory
- Different appearance

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The sponsor has performed bench tests to demonstrate the MSA100 Peak Flow Meter performs within specifications:

- Measuring range: PEF from 50 to 900 l/min; FEV1 from 0.01 to 9.99 liters
- Accuracy: PEF ± 20 l/min or± 10% of the reading; FEV1 ± 0.05L or ± 3% of the reading

Also the proposed device had met acceptance criteria of performance testing including biocompatibility (In vitro cytotoxicity, irritation and sensitization testing), electrical safety & EMC testing and ATS 2005:

1. IEC 60601-1: 2012;
2. IEC 60601-1-2: 2004;
3. AST 2005 update;
4. ISO 10993-5: 2009;
5. ISO 10993-10: 2010.

Summary of Clinical Tests:

The subject of this premarket submission, MSA100 Peak Flow Meter, did not require clinical studies to support substantial equivalence.

Conclusion:

Beijing M&B Electronic Instruments Co., Ltd considers the MSA100 Peak Flow Meter to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).