DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 6, 2017

Beijing M&B Electronic Instruments Co., Ltd.
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Services Co.,Ltd.
8-9Th Floor, R&D Building, No.26 Qinglan St, Panyu District
Guangzhou, 510006 Cn

Re: K170281
Trade/Device Name: MSA100BT Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: September 1, 2017
Received: September 5, 2017

Dear Mike 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 Industry and Consumer Education (DICE) 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" (21 CFR 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 (DICE) 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,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170281

Device Name
MSA100BT 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

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

1. SUBMITTER

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Date prepared Oct. 03, 2017

2. DEVICE

Device Name:	MSA100BT Peak Flow Meter
Common/Usual Name:	Peak Flow Meter
Regulation number	868.1860 Peak-flow meter for spirometry
Regulation Class:	II
Product Code:	BZH Meter, Peak Flow, Spirometry

3. PREDICATE DEVICE

K133975, MSA100 Peak Flow Meter
This predicate legally marketed device has not been subject to a design-related recall.
No reference device was used in this submission.

4. DEVICE DESCRIPTION

MSA100BT Peak Flow Meter is a hand-held pulmonary function measuring medical device that measures patient's maximum possible exhalation which is called peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV1). The accuracy meets American Thoracic Society (ATS) Standard 2005 Revision.

The MSA100BT is designed for pediatric to adult patients for home use and for single user, and is intended for monitoring respiratory conditions such as asthma.

The MSA100BT has an automatic memory of 250 recordings and can connect to cell phone by Bluetooth. Patients can transfer the records to phone via BLE4.0, then using app to help save and track long term.

The MSA100BT is capable of measuring PEF from 50 to 900 L/min and FEV1 from 0.01 to 9.99 L. Its measuring accuracy is ± 20 L/min or ± 10% of the reading for PEF, and ± 0.050 L or ± 3% of the reading for FEV1.

The MSA100BT is composed of main unit, turbine sensor, and mouth piece. After each use, the mouthpiece and turbine of the device should be cleaned by soap solution and water within 30 minutes.

5. INDICATIONS FOR 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 6.1 Comparison with the Predicate Device

Specification	**Predicate MSA100 Peak Flow Meter**	**Proposed MSA100BT Peak Flow Meter**	**Discussion of Differences**
K number	K133975		
Device name	MSA100 Peak Flow Meter	MSA100BT Peak Flow Meter	
Manufacturer	Beijing M&B Electronic Instruments Co., Ltd		
Indications for use	The device is intended for monitoring Peak Expired Flow (PEF) and Forced Expiratory Volume in one second (FEV1) for patient home use. The device is intended for monitoring respiratory conditions such as asthma.		Identical
Patient Population	The device is designed for pediatric to adult patients		Identical
Environment of Use	OTC		Identical
Materials	PP (mouthpiece)		Identical
Measuring range	PEF from 50 to 900 L/min FEV1 from 0.01 to 9.99 L		Identical
Measuring method	Flow: Turbine sensor Volume: Flow Integration		Identical
Accuracy	PEF ± 20 L/min or PEF ± 10% of the reading; FEV1 ± 0.05 L or FEV1 ± 3% of the reading		Identical
Measuring solution	PEF 1 L/min; FEV1 0.01 L		Identical
Data safety	Data rememorized by flash memory		Identical
Data transmission	USB wire transmission	BLE wireless transmission	Different This difference does not raise different questions of safety and effectiveness.
Memory volume	300 recordings	250 recordings	Different This difference does not raise different questions of safety and effectiveness.
Power source	AAA 1.5×2 alkaline batteries		Identical
Electrical Safety and EMC	IEC 60601-1 and IEC 60601-1-2		Identical

According to the above comparison, the proposed device is identical to the predicate device in indications for use, materials, measuring method, technical specification, power source and electrical safety.

The differences are the way of data transmission and memory, which are USB wire transmission and 300 recordings for the predicate device and BLE (Blue Smart) wireless transmission and 250 recordings for the proposed device. The differences will not raise different questions of safety and effectiveness, as both devices were demonstrated to be electromagnetic compatibility and electrical safety by testing.

In conclusion, Beijing M&B Electronic Instruments Co., Ltd. believes that the MSA100BT Peak Flow Meter is as safe and effective, and performs in a substantially equivalent manner to the predicate device.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The mouthpiece of the MSA100BT Peak Flow Meter is considered to contact directly with the human body for a duration of less than 24 hours.

The mouthpiece of the MSA100BT Peak Flow Meter in its final finished form is identical to the mouthpiece of the MSA100 Peak Flow Meter in formulation and processing, and no other chemicals have been added.

The biocompatibility evaluation for the mouthpiece was conducted in accordance with the International Standard ISO 10993-1:2009/(R)2013, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity
- Irritation
- Skin sensitization

Testing for cytotoxicity, skin sensitization and oral mucosa irritation complied with ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity and ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Testing demonstrates that the test article is non-cytotoxic, non-sensitizing, and non-oral-mucosal-irritating.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the MSA100BT Peak Flow Meter. The device complies with the IEC 60601-1:2012, standard for electrical safety and the IEC 60601-1-2:2014 standard for EMC. It demonstrates substantial equivalences to the predicate device.

Wireless testing was conducted on the MSA100BT Peak Flow Meter. The device complies with FDA's guidance: Guidance Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff.

Performance testing

Performance testing was conducted on the MSA100BT Peak Flow Meter. Technical parameters of accuracy, intra instrument repeatability, PEF inter instrument repeatability, performance of flow resistance were evaluated in the performance

testing, according to Standards of Spirometry (2005 Revision). All of the tested parameters meet the requirements in the standards. The performance of the proposed device is demonstrated to be comparable with the predicate device in the comparison testing, so it is concluded that the proposed device is substantially equivalent to the predicate device.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern. Software validation demonstrated that the software functions as specified in the software requirement specifications. It demonstrates substantial equivalences to the predicate device.

Animal Study

The subject of this premarket submission, MSA100BT Peak Flow Meter, did not require animal studies to support substantial equivalence.

Clinical Study

The subject of this premarket submission, MSA100BT Peak Flow Meter, did not require clinical studies to support substantial equivalence.

8. CONCLUSION

The differences between the MSA100BT Peak Flow Meter and its predicate device do not raise different questions of safety and effectiveness. The non-clinical data including the performance testing supports that the MSA100BT Peak Flow Meter is substantially equivalent to the predicate device.