September 14, 2018

MicroBase Technology Corporation
% Paul Dryden
Consultant
MicroBase Technology Corporation
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K180871
Trade/Device Name: Portable Nebulizer (MBPN002)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: August 15, 2018
Received: August 16, 2018

Dear Paul Dryden:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180871

Device Name

Portable Nebulizer (MBPN002)

Indications for Use *(Describe)*

The Portable Nebulizer (MBPN002) is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital/institutional settings, home care use, schools, and long term care facilities.

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

XX 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

MicroBase Technology Corporation
No. 756, Jiadong Road
Bade District, Taoyuan City 33464, Taiwan

Official Contact:	Molly Hsieh General Manager Tel - 011-886-3-376-7555
Proprietary or Trade Name:	Portable Nebulizer (MBPN002)
Common/Usual Name:	Nebulizer (Direct Patient Interface)
Classification Name:	Nebulizer (Direct Patient Interface) Product Classification – CAF 21 CFR 868.5630 Class II
Predicate Device:	K170916 MicroBase Portable Nebulizer

Device Description:
The Portable Nebulizer (MBPN002) is a small, handheld general purpose nebulizer which utilizes vibrating mesh technology to generate aerosol.

Modification:
The MicroBase Portable Nebulizer was modified to allow for connection to a 5 Volt Class II, IEC 60601-1 compliant external power supply. The device will still contain internal primary batteries. The power input jack interrupts (opens) the connection to the batteries when the external supply is plugged in so the batteries will not be connected to it (i.e., preventing them from charging).

When operating on battery power the Main unit converts the 3.0V nominal from the batteries to 15.0V for operation of the unit. The Main Unit thus operates on 15.0V regardless of power source (battery or external Power) there is no impact on nebulizing properties or performance.

There are no differences between the subject device and the predicate with respect to indications for use.

Components:
The **Medication Cup** contains the nebulizing module where aerosol will be generated. Prescribed medication is placed in the Cup, nebulized and inhaled via the integral mouthpiece.

The Medication Cup is single patient, multi-use. Cleaning is performed after each use by rinsing with distilled water and disinfected as described in the labeling via immersion in boiled water for 10 minutes.

The cup medication capacity is 6 ml.

The medication cup is identical to that cleared in K170916.

The **Main Unit** contains the 2 "AA" batteries and firmware to control the vibrating mesh module in the Medication Cup. It is being modified to provide provision for external power from an IEC 60601-1 compliant power supply as described in Modification above.

Portable Nebulizer aerosolizes upon turning on by pressing the ON/OFF button and turns off by pressing again or automatically after treatment completion in 30 minutes. To monitor nebulization status and device operating condition, there are different LED colors shown. Normal working condition is indicated by a green while an orange color signifies a malfunction.

The Main Unit is identical to that cleared in K170916 except for the provision for external power from an IEC 60601-1 compliant power supply.

Indications for Use:
The Portable Nebulizer (MBPN002) is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital/institutional settings, home care use, schools, and long term care facilities.

Principle of Operation / Technology:
The Portable Nebulizer (MBPN002) operates by electrically activating piezoelectric ceramic actuator (PZT) which then transduces the vibration generated to the adjacent supporting plate and polymer mesh bearing numerous apertures. The vibration actively pushes out the liquid medication by physically breaking surface tension of the solution through mesh holes thereby achieving final nebulization. Aerosol generation can subsequently be modulated the vibration frequency that is controlled by the firmware stored within Main Unit to maintain a frequency of approximate 117 kHz, nebulization rate of $\geq$ 0.25 ml/min and a power consumption of <1.5 W.

Table 1 – Performance Specifications

Features	Modified Portable Nebulizer
Indications for use **Environment of Use** **Patient Population**	The Portable Nebulizer (MBPN002) is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years old or greater), defined by the prescribed medication, and adult patients in hospital/institutional settings, home care use, schools, and long term care facilities.
Contraindications	None
Vibrating mesh technology	Yes
Software driven	Yes - firmware
Patient Interface	Mouthpiece
Nebulizer components to be reused	Medication Cup and mouthpiece
Cleaning / Disinfecting	Rinsed in distilled water Disinfect via boiled water
Operating conditions	10ºC to 40ºC 30% to 85% RH
Storage conditions	-20ºC to 70ºC, 20% to 75% RH
Power Source	DC – 2 – AA Alkaline batteries External AC power from a provided Class II - IEC 60601-1 compliant power supply

Comparison to Predicate

Tables 2 provides a comparison of the modified device to the predicate.

Table 2 – Comparison of Modified vs. Predicate Device

Features	Predicate Portable Nebulizer K170916	Modified Portable Nebulizer Model MBPN002	Comment
Indications for use	The Portable Nebulizer is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years old or greater), defined by the prescribed medication, and adult patients in hospital/institutional settings, home care use, schools, and long term care facilities.	The Portable Nebulizer (MBPN002) is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years old or greater), defined by the prescribed medication, and adult patients in hospital/institutional settings, home care use, schools, and long term care facilities.	Identical
Patient Population	The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients	The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients	Identical
Environment of Use	Hospital/institutional settings, home care use, schools, and long term care facilities.	Hospital/institutional settings, home care use, schools, and long term care facilities.	Identical
Contraindications	None	None	Identical
Principle of Operation	Vibrating mesh	Vibrating mesh	Identical
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation	Identical
Compressed gas source	None needed	None needed	Identical
Reservoir volume	6 ml	6 ml	Identical
Nebulization rate	$\geq$ 0.25 ml/min	$\geq$ 0.25 ml/min	Identical
Duration of Use	Single patient, multi-use	Single patient, multi-use	Identical
Nebulizer components cleanable	Yes	Yes	Identical
Software driven	Yes	Yes	Identical
Power source	2 – “AA” battery	2 – “AA” battery or External power from provided external Class II IEC 60601-1 compliant supply	Adds the option of external power. No change to device performance.
Power consumption	< 1.5 W	< 1.5 W	Identical
Weight	74 gm w/o batteries	74 gm w/o batteries	Identical
Dimensions (mm)	77 x 41 x 73	77 x 41 x 73	Identical
Operating Conditions	10 to 40ºC / 30-85% RH	10 to 40ºC / 30-85% RH	Identical
Storage Conditions	-20 to + 70ºC / 20-75% RH	-20 to + 70ºC / 20-75% RH	Identical

Features	Predicate Portable Nebulizer K170916	Modified Portable Nebulizer Model MBPN002	Comment
User interface	On/Off switch LED indicators	On/Off switch LED indicators	Identical
Standards met	ANSI/AAMI/ES60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11	ANSI/AAMI/ES60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11	Identical
Materials per ISO 10993-1	External Communicating (Indirect gas pathway) Tissue / Bone / Dentin communicating Duration of Use – permanent (> 30 days) And Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)	External Communicating (Indirect gas pathway) Tissue / Bone / Dentin communicating Duration of Use – permanent (> 30 days) And Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)	Identical
Software			
Level of Concern	Moderate	Moderate	Identical
Device Specific	Yes	Yes	Identical
Dependent on external devices	No	No	Identical
Signals	LED and tone sounds	LED and tone sounds	Identical

Substantial Equivalence Discussion

The Portable Nebulizer is viewed as substantially equivalent to the predicate device because:

Indications for Use – The indications for use are to aerosolize commonly prescribed medications which are to be delivered via a nebulizer.
Discussion - The indications for use are identical for the modified device and the predicate – MicroBase Portable Nebulizer K170916.

Patient Population – The patient population of adult and pediatric (defined by the prescribed medication) patients that is consistent with the indications for the aerosol medication. This is identical the predicate MicroBase Portable Nebulizer K170916.
Discussion - The patient population is identical MicroBase Portable Nebulizer K170916.

Environment of Use – The environments of use are common and usual for handheld nebulizers, namely Hospital/institutional settings, home care use, schools and long term care facilities.
Discussion – The environment of use is identical for the modified device and the predicate – MicroBase Portable Nebulizer K170916.

Technology – The design as a vibrating mesh nebulizer which is the identical principle of operation.
Discussion – The technology is identical for the modified device and the predicate MicroBase Portable Nebulizer K170916.

Summary of Non-Clinical Performance Testing

The MicroBase Portable Nebulizer (MBPN002) was tested for:

- Electrical Safety, EMC, Home use

The above tests are specific to the modification. Other testing that was performed on the predicate, K170916, remain unchanged. Those tests were

- Shelf-life, Useful-life, and Durability Testing
- Simulated Life Cycle testing
- Cleaning
- Particle Characterization per Cascade Impactor
- Intra- and Inter- Sample Variability

These tests are independent of the power source and the modification specific to this submission.

Electrical Safety and **Electromagnetic Compatibility (EMC)**
Electrical safety and EMC testing were conducted on the device. Testing established that, with respect to electrical safety, the device meets the applicable requirements of: (1) ANSI/AAMI/ES 60601-1:2005+A1: 2012; (2) IEC 60601-1-2:2014; (3) IEC 60601-1-11:2015.

Verification and Validation Testing
MicroBase performed a Risk / Hazard Analysis in accordance to company procedures which was used to assess the impact of the modifications listed above. Based on the Risk / Hazard Analysis an identification of the verification and / or, validation activities required was made and appropriate methods or tests and the applicable pass / fail criteria applied were performed.

Biocompatibility
The materials in patient / drug contact are characterized as:

- External Communicating (Indirect gas pathway)
- Tissue / Bone / Dentin communicating
- Duration of Use – permanent (> 30 days)

And

- Surface Contact
- Mucosal membrane
- Duration of Use – permanent (> 30 days)

Discussion - We performed ISO 10993-1 tests to support biocompatibility. They included:

- Cytotoxicity
- Sensitization
- Irritation
- Sub-chronic Systemic toxicity
- Acute Systemic Toxicity
- Leachable and Extractables with Risk Based Assessment
- Gas Emission VOC plus Inorganic compounds - CO, CO_2, and Ozone
- $PM_{2.5}$

Under the parameters of the tests it is concluded that they are biocompatible, and that there are no new issues of biocompatibility regarding their use as intended.

Cleaning and Disinfection Validation

The modification does not affect the device design or materials as it relates to cleaning and disinfection. The predicate testing performed microbiological efficiency control tests to validate the nebulizer cleaning and disinfection methods in the labeling. Testing involved validation of: (1) a manual cleaning method and a thermal disinfection method. All testing concluded that the nebulizer could be cleaned and disinfected effectively by the listed methods

Particle Characterization

Particle characterization performance is the same as the predicate device as the Main Unit operates at 15 V regardless of the power source: battery or AC power. Therefore there is no change in the aerosolization performance.

Particle size characterization (MMAD) was verified after two years of real-time aging using both cascade impactor technique and laser light scattering technique and is equivalent to that presented in K170916.

Substantial Equivalence Conclusion

The indications for use, patient population, environment of use, technology principle of operation and performance of the modified device is identical to the predicate cleared under K170916 therefore we conclude that the modified device can be determined to be substantially equivalent to the predicate.