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

September 30, 2014

Omron Healthcare, Incorporated
C/O Mr. Paul Dryden
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, FL 34134-2958

Re: K141140
Trade/Device Name: Omron Compressor Nebulizer Systems –NE-C802
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: August 28, 2014
Received: August 29, 2014

Dear Mr. 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. 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.
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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)*
K141140

Device Name
NE-C802

Indications for Use *(Describe)*
The NE-C802 Compressor Nebulizer System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The system is designed for use with pediatric (3 year old and greater) and adult patients in the home, hospital, and sub-acute 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)*

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Omron Healthcare, Inc.
1200 Lakeside Drive Tel – 847-247-5626
Bannockburn, IL 60015 USA Fax – 847-680-6269

Official Contact: Renee Thornborough – Director, Quality & Regulatory

Proprietary or Trade Name: NE-C802

Common/Usual Name: Nebulizer (direct patient interface)

Classification Name/Code: CAF, Class 2, Nebulizer (direct patient interface)
CFR 870.1130

Device: NE-C802

Modified Device: Omron – NE-C801 – K110860

Device Description:
The Omron Model NE-C802 is a standard nebulizer compressor system with an integral compressor and handheld, pneumatic nebulizer intended for general purpose use. It is powered by standard AC. This is a modification of the NE-C801 cleared under K110860.

The modifications to the device do not change the intended use of the predicate device. The modifications to the device do not alter the fundamental scientific technology. As there are no changes in hardware that will impact performance, there is no need to validate the changes through a clinical investigation.

Indications for Use:
The NE-C802 Compressor Nebulizer System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The system is designed for use with pediatric (3 year old and greater) and adult patients in the home, hospital, and sub-acute settings.

Contraindications:
None

Summary of Modifications:
The modifications to the device do not change the intended use of the predicate device. The modifications to the device do not alter the fundamental scientific technology. As there are no changes in hardware that will impact performance, there is no need to validate the changes through a clinical investigation.

Modifications:

- Minor changes to nebulizer design
- Changes to physical dimensions
- Change to compressor design to make it smaller and lighter weight

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There is no change in intended use, including patient population and environment of use. There is no change in contraindications.

Performance Testing:

Verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. **Table 5.1** summarizes the difference, **Table 5.2** equivalence comparison, and **Table 5.3** the testing.

Table 5.1 – Description of the modifications of the New Model NE-C802 vs. the Predicate

Features	New model NE-C802	Predicate (K110860) NE-C801
Compressor	Roller – 3 valves	Roller – 4 valves
Power	DC 6V	DC 12V
Operating pressure and flow from compressor	≤ 52 Kpa ≥ 1.2 lpm	≤ 54 Kpa ≥ 2.54 lpm
Nebulizer design	Design change to some nebulizer components to improve air flow but still pneumatic and principle of operation is the same	
Delivery rate	0.25 ml / min	0.3 ml / min
Particle size (MMAD) in um	@ 15L/min Pulmicort – 4.43 μm Intal – 3.78 μm Salbutamol – 3.25 μm @ 32L/min Pulmicort – 4.08 μm Intal – 3.37 μm Salbutamol – 2.94 μm	@ 15L/min Pulmicort – 4.89 μm Intal – 3.33 μm Salbutamol – 3.38 μm @ 32L/min Pulmicort – 4.37 μm Intal – 2.79 μm Salbutamol – 2.72 μm
Non-significance of Variance and mean difference (p value)		
Dimensions (mm)	85mm (W) x 43mm (H) x 115mm (D)	142 mm (W) x 98 mm (H) x 72 mm (D)
Weight (kg) without battery	190 gm	270 gm
Reservoir size	10 ml	7 ml

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Table 5.2 – Comparison and Equivalence of New Model NE-C802 and the Predicate

Features	New NE-C802	Predicate (K110860) NE-C801
Indications for use	The NE-C802 Compressor Nebulizer System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders.	The NE-C801 Compressor Nebulizer System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders.
Environment of Use	Home, Hospital, Sub-acute Institutions	Same
Patient Population	Pediatric (3 years and older) to adult	Pediatric and adult
Contraindications	None	None
Pneumatic compressor	Yes	Yes
Pneumatic nebulizer	Yes	Yes
Software driven	No	No
Materials in patient contact	Polypropylene and PVC	ABS, Polypropylene and PVC
Patient Interface	Mouthpiece or mask	Mouthpiece or mask
Standards met	IEC 60601-1:2005 IEC 60601-1-2:2007 IEC 60601-1-11:2007 IEC 62366:2007 ISO10993-1:2009 ISO10993-5:2009 ISO10993-10:2010	IEC60601-1:1988 +A1:1991+A2:1995 IEC60601-1-2:2007 ISO10993-1:2009 ISO10993-5:2009 ISO10993-10:2009
Nebulizer components cleanable	Yes	Yes
Operating conditions	10°C to 40°C 30% to 85% RH	Same
Storage conditions	-20°C to 60°C 10% to 95% RH	Same
Power Source	AC	AC

The differences between the proposed device and the predicates are:

- Physical size
- A modification to nebulizer

It is our view that these are not significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

Table 5.3 – Particle Characterization results

A series of aerosol performance tests were performed using an 8 stage cascade impactor at a sampling flow rate of 15 l/min equipped with a USP <601> induction port throat. Aerosol was sampled directly from the outlet. A summary of results is listed below with intervals given for a 99% confidence level.

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Characteristic	Device NE-C802 (NEW)			Predicate Device – NE-C801 K110860		
	Pulmicort	Intal	Salbutamol	Pulmicort	Intal	Salbutamol
	250 ug.ml	10 mg/ml	5 mg/ml	250 ug.ml	10 mg/ml	5 mg/ml
MMAD (um)						
15 lpm	4.89	3.33	3.38	4.43	3.78	3.25
32 lpm	4.37	3.79	2.72	4.08	3.37	2.94
GSD						
15 lpm	2.4	2.8	2.9	2.2	2.4	2.7
32 lpm	2.55	3.2	3.4	2.32	2.7	2.89
Total Delivered Dose (ug)						
15 lpm	385	12993	7483	395	13567	7650
32 lpm	392	12992	7494	378	12533	7716
Total Delivered Dose Fraction (%)						
15 lpm	76%	65%	74%	80%	69%	78%
32 lpm	78%	65%	75%	81%	64%	79%
Respirable Fraction (0.5-5 um) (%)						
15 lpm	50%	60%	56%	55%	59%	59%
32 lpm	54%	64%	57%	58%	62%	60%
Total Respirable Dose (0.5-5 um) (ug)						
15 lpm	1.93	78.27	41.63	2.17	80.13	44.9
32 lpm	2.12	82.4	43.03	2.39	77.86	46.24

Summary of results –

The NE-C802 was found to be substantially equivalent on all performance areas except as noted below. Those differences are in GSD and Ultra-fine particle fraction. Neither of which is associated with the therapeutic performance of the proposed device.

The statistical analysis was done with a 99% confidence interval.

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The Model NE-C802 is viewed as substantially equivalent to the predicate device because:

Indications –
The Indications for Use are as a general purpose nebulizer and compressor system which is identical to predicate – Omron NE-C801 (K110860).
Discussion – We have not changed the indications for use statement, only defined the pediatric population to 3 years and older, which has been a recent FDA request.

Technology –
The technology of the compressor is identical compressor technology to predicate – Omron NE-C801 (K110860). The technology of the pneumatic nebulization is identical nebulizer technology to predicate – Omron NE-C801 (K110860).
Discussion – The modifications to compressor, smaller and lighter weight has not changed the technology. As to the nebulizer changes, this is still a pneumatic nebulizer to aerosolize medications. The changes have been for simplification and efficiency of performance. The particle characterization performance demonstrates that the 2 devices perform substantially equivalent.

Materials –
The materials in the gas and fluid pathway are identical to predicate device, Omron NE-C801 (K110860)**.**
Discussion – The materials are identical to our own predicate device are have the identical patient contact, exposure, and duration of use. The use of these materials has been determined to be safe by FDA under previous submission reviews.

Environment of Use –
The environment of use is – home, hospital and sub-acute care settings which are identical to predicate – Omron NE-C801 (K110860).
Discussion - There have been no changes in the environment of use and thus the proposed device can be found substantially equivalent to the predicate.

Patient Population –
The patient population is pediatric and adult which is identical to predicate – NE-C801 (K110860).
Discussion – We have not changed the patient population, but as requested by FDA, there are subsets of "pediatric" populations and we have added clarification of this in our indications for use. It is common practice that nebulizers may be used with patients that are 3 years and old, or can follow verbal instructions. Our added language does not alter the indications for use, but only to supports FDA's request for clarification of "pediatrics" population.

Non-clinical Testing –
We have performed a number of performance tests which are identical to those done with the predicate, Omron NE-C801 (K110860). These included:

- IEC 60601-1
- IEC 60601-1-2

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- Cascade Impactor particle characterization testing with 3 devices for 3 runs with 3 drugs
- Compressor testing
    - VOC testing per EPA TO-15
    - CO, CO_2 testing EPA Part 60
    - Ozone testing per OSHA method ID 214
    - $PM_{2.5}$ testing per NIOSH NMAM 0600
- Cleaning
- Simulated life and age testing
- Mechanical testing

Discussion – The non-clinical testing demonstrated that the performance of the proposed device was equivalent to the predicate Omron NE-C801 (K110860).

Clinical Testing –
There was no clinical testing performed.

Substantial Equivalence Conclusion -

The proposed device has been found to be substantially equivalent to the predicate. Differences between the proposed device and the predicate do not raise new questions of safety or efficacy.