DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 14, 2017

Pari Respiratory Equipment, Inc.
Michael Judge
VP, Operations And Regulatory Affairs
2412 Pari Way
Midlothian, Virginia 23112

Re: K162785
Trade/Device Name: Velox Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: March 8, 2017
Received: March 8, 2017

Dear Mr. Judge:

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" (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 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,

Michael J. 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)*
K162785

Device Name
Velox Nebulizer System

Indications for Use *(Describe)*
The Velox Nebulizer System is a handheld nebulizer that is to be used with patients for whom doctors have prescribed medication for nebulization. It is intended for adult and pediatric patients 4 years and older who can coordinate breathing through a mouthpiece, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.

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.

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SECTION 6: 510(K) SUMMARY

1. Submitter

PARI Respiratory Equipment, Inc.
2412 PARI Way
Midlothian, Virginia 23112

Phone: 804-253-7274
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Contact Person: Mike Judge x 269
Date Prepared: September 15, 2016

2. Device Name

Name of Device:	Velox™ Nebulizer System
Common or Usual Name:	Nebulizer
Classification Name:	Nebulizer, Direct Patient Interface (21 CFR 868.5630)
Regulatory Class:	II
Product Code:	CAF

There are no other variants or model numbers of this device.

3. Legally Marketed Predicate Device

The following predicate device has not been subject to a design-related recall.

a. Primary Predicate Device

eRapid® Nebulizer System, K112859

Additionally, the Philips Respironics I-Neb AAD System, cleared under K042991, is used in this 510(k) submission as a reference device.

4. Device Description

The Velox Nebulizer System is a portable, reusable, single-patient use, handheld electronic nebulizer that uses a piezo-driven, micro-perforated vibrating membrane technology to aerosolize liquid medications for the treatment or prophylaxis of respiratory diseases. It is to be used with adult and pediatric patients for whom doctors have prescribed medication, i.e. it is for prescription use only. It may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments. It is provided non-sterile.

The device consists of two major components. One of these components is the nebulizer itself, which has the following materials in its construction: (1) polypropylene; (2); thermoplastic elastomer; (3) stainless steel; (4) piezo-ceramic; (5) capton; and, (6) medical grade adhesives. It contains, as subcomponents, the following: (1) a medication cap, (2) a medication reservoir, (3) an aerosol head, (4) an aerosol chamber; and, (5) a mouthpiece.

The second major component is a Controller that is attached to the Nebulizer for its operation. This component, the body of which is constructed of acrylonitrile butadiene styrene and thermoplastic elastomer, has the following principal internal subcomponents: (1)

a circuit board; (2) a USB connector; (3) a patient interface (on/off switch); and (4) AA battery housing.

The controller's functions are to; (1) conduct power pre-processing; (2) supervise, through incorporated software, the nebulizer's aerosol generation; and, (3) generate optical and acoustical feedback to the user on nebulization status and out-of-range parameters.

The incorporated software is device-specific and: (1) controls the power to the aerosol head, i.e., either to have the aerosol head active and generate aerosol, or shut-off; (2) controls optical and acoustical feedback to the user; and; (3) is not dependent for its operation on any external devices, such as a monitor, printer, keyboard or mouse.

Energy sources for the device are provided by: (1) connection to a mains power source, via an AC Power Supply; or, (2) disposable/rechargeable AA batteries.

The device has two associated accessories: (1) a cleaning aid, branded VELOXcare, that assists in debris removal from the membrane prior to cleaning; and, as heretofore noted, (2) an AC Power Supply to provide mains power to the device when desired or required.

5. Mechanism of Action

The Velox Nebulizer System's mode of action is permanent, i.e., once the on/off switch is on the controller pressed, permanent nebulization occurs until the medication is nebulized. There is no pause function. Further, there is no breath trigger or interrupter.

Nebulization is accomplished as follows. When the on/off button is pressed the controller sends an electrical charge to the aerosol head in the nebulizer. The charge alternation causes the piezo-actuator to vibrate. Vibration motion then builds up a positive pressure in the boundary layer of the liquid column, ejecting the fluid through the holes as droplets and creating the aerosol on the front side of the membrane. This aerosol is deposited vertically into the aerosol chamber. Once in the chamber it is available for inhalation by the patient.

The inhalation is via a breath-enhanced two-way valve system. During inhalation the inhalation valves open to allow fresh air to enter the aerosol chamber. This inhaled fresh air stream, takes the aerosolized medication, with minimum depositional loss, through the mouthpiece into the patient's respiratory tract. Note that, during inhalation, the exhalation valve on the mouthpiece is closed, preventing any aerosol dilution on its way to the patient. During exhalation, the inhalation valves close and the exhalation valve opens, driving the expired air out of the mouthpiece.

6. Indications for Use

The Velox Nebulizer System is a handheld nebulizer that is to be used with patients for whom doctors have prescribed medication for nebulization. It is intended for adult and pediatric patients 4 years and older who can coordinate breathing through a mouthpiece, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.

The foregoing statement for the subject device is identical to that of the predicate eRapid® device (with the exception of the "4 years and older who can coordinate breathing through a mouthpiece" restriction. The indications are substantially equivalent; the subject device indication statement simply provides a quantification of patient age, and clarification of the patient's breathing

coordination ability at that age). Further, both the subject and predicate device have the same intended use.

7. Comparison of Technological Characteristics with the Predicate Device

Table 1. Substantial Equivalence Comparison

PRODUCT	VELOX NEBULIZER SYSTEM	ERAPID NEBULIZER SYSTEM
DEVICE CLASSIFICATION	CAF, Nebulizer (direct patient interface), 21 CFR 868.5630	CAF, Nebulizer (direct patient interface), 21 CFR 868.5630
510K NO.	**n/a**	K112859
MANUFACTURER (REG. NO.)	PARI Respiratory Equipment, Inc. (2954963)	PARI Respiratory Equipment, Inc. (2954963)
INTENDED USE	The Velox is a handheld nebulizer that will be used with patients for whom doctors have prescribed medication for nebulization.	The eRapid is a handheld nebulizer that will be used with patients for whom doctors have prescribed medication for nebulization.
Environment of use	Home care, nursing home, sub-acute institution, or hospital	Home care, nursing home, sub-acute institution, or hospital
Target Population	Adult and pediatric patients 4 years and older who can coordinate breathing through a mouthpiece	Adult and pediatric
Prescription Use	Rx Only	Rx Only
METHOD OF OPERATION		
Technology Used	Micro-perforated vibrating membrane technology: active, vibrating membrane	Micro-perforated vibrating membrane technology: active, vibrating membrane
Aerosol Direction/Output	Vertically sprayed into aerosol chamber, cleared by inspiratory flow	Horizontally sprayed into aerosol chamber, cleared by inspiratory flow
Breath Enhanced/ Controlled/ Triggered	Breath enhanced two-way valve system. Permanent nebulization - no breath trigger or control.	Breath enhanced two-way valve system. Permanent nebulization - no breath trigger or control.
Fluid Delivery – Generator	Direct contact between aerosol head and fluid in sealed chamber (medication reservoir).	Direct contact between aerosol head and fluid in sealed chamber (medication reservoir).
Configuration	Controller component is connected directly to the nebulizer component. No connection cord for operation.	Nebulizer and controller are separate components, joined by a connection cord for operation.
Automatic Shut-off	Yes. Automatic shut-off when: (1) medication reservoir is empty; (2) out-of-range parameters are detected; or (3) programmed maximum operating time) is reached.	Yes. Automatic shut-off when: (1) medication reservoir is empty; (2) out-of-range parameters are detected; or (3) programmed maximum operating time) is reached.

PRODUCT	VELOX NEBULIZER SYSTEM	ERAPID NEBULIZER SYSTEM
DESIGN CAPACITIES		
Medication Reservoir Min. Fill Max. Fill Residue	2.0 mL 6.0 mL Approx. 1.0 ml residue (depending on filled volume)	2.0 mL 6.0 mL Approx. 1.0 ml residue (depending on filled volume)
PERFORMANCE		
MMAD	Mass Median Aerodynamic Diameter of subject device is slightly lower than that of eRapid.	
GSD	Geometric Standard Deviation of subject device is substantially equivalent to that of eRapid	
RF	Respirable Fraction of subject device is slightly higher than that of eRapid	
RD	Respirable Dose of subject device is substantially equivalent to that of eRapid	
SOFTWARE		
Level of Concern	Moderate	Moderate
Device-Specific	Yes	Yes
Dependent on External Devices	No	No
Function	By continuous loop: (1) conducts power pre-processing; (2) supervises the nebulizer's aerosol generation; and (3) communicates to the user on the operational status of the device and out-of-range parameters. These functions are performed continuously until the medication reservoir is empty, out-of-range parameters are detected, or programmed maximum operating time (T_{max}) is reached. It should be noted however, that, unlike the predicate device's software, the subject device's software has: (1) no integral pause function that enables treatment interruption for user convenience; and, (2) no separate cleaning aid mode that allows the user to operate a cleaning aid.	By continuous loop: (1) conducts power pre-processing; (2) supervises the nebulizer's aerosol generation; and (3) communicates to the user on the operational status of the device and out-of-range parameters. These functions are performed continuously until the medication reservoir is empty, out-of-range parameters are detected, or programmed maximum operating time (T_{max}) is reached. It should be noted however, that the predicate device's software has: (1) an integral pause function that enables treatment interruption for user convenience; and, (2) a separate cleaning aid mode that allows the user to operate a cleaning aid.
Audiovisual Signals	LED and tone sounds concerning battery level, operational status and failure mode.	LED, tone sounds and illuminated display showing graphical symbols concerning battery level, operational status and failure mode.
ELECTRICAL CONNECTION		

PRODUCT	VELOX NEBULIZER SYSTEM	ERAPID NEBULIZER SYSTEM
Power Wattage	< 2.0 W under normal load	< 2.0 W under normal load
AC Power Supply		
Input	100-240 VAC / 50-60 Hz	100-240 VAC / 50-60 Hz
Output	5 V	12 V
Battery Operation		
AA Disposable	3 x 1.5 V	4 x 1.5 V
AA Rechargeable	3 x 1.2 V	4 x 1.2 V
Classification According To IEC 60601 - 1		
Type of electric shock protection (AC Power Supply)	Protection Class II	Protection Class II
Degree of protection from electric shock of the part used (nebulizer)	Type BF	Type BF
Degree of protection against water ingress in accordance with EN 60529 (IP rating)	IP-22	No protection
Degree of protection when used in the presence of flammable mixtures of anesthetics with air, with oxygen, or with nitrous oxide	No protection	No protection
Operating Mode	Continuous operation	Continuous operation
NEBULIZER MATERIALS		
Medication Cap	PP, TPE	PP, POM, TPE
Medication Reservoir	PP, TPE	–
Fluid Feed	N/A	PP, TPE
Headmount	N/A	PP, stainless steel
Housing	PP, TPE	N/A
Aerosol Head	Stainless steel, piezoceramic, polyamide film, adhesive	Stainless steel, piezoceramic, polyamide film, adhesive

PRODUCT	VELOX NEBULIZER SYSTEM	ERAPID NEBULIZER SYSTEM
Inhalation Valve	TPE	Silicone
Aerosol chamber	PP	PP
Mouthpiece	PP	PP
Exhalation Valve	TPE	Silicone
MECHANICAL		
Dimensions Nebulizer (L /W /H) Controller (H /Ø)	 145 x 61 x 65 mm 70 x 61 x 92 mm	 145 x 50 x 63 mm 40 mm x Ø 116 mm
Weight (approx.) Handset w/o med. System w/batt.	 45g 285g	 55g 300g
CLEANING / DISINFECTION		
Cleaning	Cleaning with detergent and water.	Cleaning with detergent and water.
Disinfection	Disinfection with chemical (Control III) or thermal means (boiling).	Disinfection with chemical (Control III) or thermal means (boiling or autoclaving).
Cleaning Aid	PP/TPE accessory to mechanically rinse the aerosol head membrane pores by means of backwashing (back flushing). Device unique - not interchangeable with other PRE vibrational technology devices.	PP/TPE accessory to mechanically rinse the aerosol head membrane pores by means of backwashing (back flushing). Interchangeable with other PRE vibrational technology devices.

a. Velox and Primary Predicate eRapid

Similarities are that both the Velox and the predicate eRapid device are identical in purpose, function, core technology and energy sources. That is, they are portable, reusable, single-patient use, handheld electronic nebulizers that use a piezo-driven, micro-perforated vibrating membrane technology to aerosolize liquid medications for the treatment or prophylaxis of respiratory diseases. They are to be used with adult and pediatric patients for whom doctors have prescribed medication, i.e. they are for prescription use only. They may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments. Energy sources for the devices are provided by: (1) connection to a mains power source, via an AC Power Supply; or, (2) disposable/rechargeable AA batteries.

Both the Velox and the predicate eRapid employ breath enhanced, two-way valve systems. Further, both devices have permanent modes of action, i.e., once the on/off switch on the controller is pressed, permanent nebulization occurs until the medication is nebulized. Neither has any breath trigger or interrupter. Fluid delivery / generation for both devices is by direct contact between the aerosol head and the fluid in sealed medication reservoir.

System design and mode of action differ. Relative to design the Velox: (1) has fewer separate Nebulizer operating parts than those of the predicate eRapid; (2) has no connection cord linking its controller and nebulizer, as is the case with the predicate eRapid; (3) the direction of generated spray from the aerosol head to the aerosol chamber is vertical in the Velox, as opposed to horizontal in the predicate eRapid; and, (4) because the Velox's nebulization is fairly rapid, it has no pause function like that in the eRapid.

8. Performance Data

The following performance data were provided in support of an SE determination.

a. Biocompatibility Testing

The nebulizer's medication reservoir, aerosol head and tubing from the cup to the mouthpiece (aerosol chamber and inside of the mouthpiece) are permanent exposure, external-communicating devices (tissues, bone, dentin). The outside of the mouthpiece is a permanent exposure, surface-mucosal membrane contact component.

A biocompatibility evaluation for the Velox device was conducted in accordance with FDA's 2016 Guidance entitled, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The evaluation included the following tests: (1) *In-Vitro* Cytotoxicity, (2) Genotoxicity; (3) Implantation; (4) Irritation/Intracutaneous Reactivity; and, (5) Skin Sensitization/Delayed Type Hypersensitivity.

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

Gas Path Testing

The emitted air quality of the PARI Velox device was evaluated to determine whether it may produce potentially harmful gases, VOCs, or particulates, as follows:

1) Ozone Gas Analysis
2) Carbon Monoxide and Carbon Dioxide Gas Analysis
3) Volatile Organic Compounds Analysis
4) Particular Matter Analysis (EPA PM2.5)

All air quality tests concluded that the subject device meets applicable standards and does not introduce new issues of safety pertaining to emitted air.

b. **Electrical Safety** and **Electromagnetic Compatibility (EMC)**

Electrical safety and EMC testing were conducted on the device's controller and AC power supply. Testing establishes that, with respect to electrical safety, the Velox meets

the applicable requirements of: (1) *IEC 60601-1*; (2) *IEC 60601-1-6*; (3) *IEC 60601-1-11*; and (4) IEC *62366*. Further, EMC testing establishes that the Velox Nebulizer System and AC Power Supply meet the applicable requirements of *IEC 60601-1-2:2007*.

c. Software Verification and Validation Testing

Verification and validation testing was conducted in accordance with, and documentation was provided as recommended by FDA's Guidance 337, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*". The software for this device is of a "moderate" level of concern, since a failure or latent flaw in the software could lead to a delay in delivery of appropriate medical care.

d. Aerosol Characterization

An aerosol characterization (particle size distribution) by next generation impaction was made with the Velox and the eRapid predicate. With respect to aerosol performance the Velox's: (1) MMAD was slightly lower than that of the predicate eRapid; (2) GSD was very similar to that of the predicate eRapid; (3) RF (Respirable Fraction) was slightly higher than that of the predicate eRapid; and, (4) RD (Respirable Dose) was very similar compared to that of the predicate eRapid.

e. Simulated Use Test

Testing was made to determine if the Velox remained within specification over its envisioned lifetime usage of one year, using 365 nebulizations and 52 weekly disinfection cycles. The testing concluded that the device remained within those specifications and the nebulizer could be cleaned and disinfected effectively by use of the methods stated in the IFU.

f. Mechanical Testing

1) Packaging Drop Test

A drop test was performed, based on *EN/ISO 2248:1985, Complete, filled transport packages— Vertical impact test by dropping*, to determine that the design and strength of the Velox Nebulizer System sales/transport packaging is sufficient for transport, storage and sales. The testing concluded that the packaging is satisfactory for the envisioned uses.

2) Environmental Conditions Test

An environmental conditions test was conducted in order to define the device's optimal operating conditions of temperature and relative humidity for incorporation into the IFU. The testing established these environmental conditions.

g. Cleaning and Disinfection Validation

Microbiological efficiency control tests were conducted in order to validate the nebulizer cleaning and disinfection methods in the IFU. Testing involved validation of: (1) a manual cleaning method; (2) a chemical disinfection method; and, (3) two thermal disinfection methods. All testing concluded that the nebulizer could be cleaned and disinfected effectively by use of the methods stated in the IFU.

9. Conclusion

Based upon the foregoing the Velox™ Nebulizer System is substantially equivalent to the eRapid Nebulizer System, which is a legally marketed predicate device. As heretofore noted the Velox's indications for use and intended use are substantially equivalent to the predicate device. Further, the performance testing and comparison show that this device is as safe and as effective as the predicate device.