August 11, 2023

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

Re: K223840
Trade/Device Name: eRapid Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: July 5, 2023
Received: July 10, 2023

Dear Michael 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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Office of Product Evaluation and Quality
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223840

Device Name
eRapid NCP Nebulizer System

Indications for Use *(Describe)*
The eRapid NCP Nebulizer System is to be used with patients for whom doctors have prescribed medicine for nebulization. It is intended for adult and pediatric patients age 4 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.

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

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1. Submitter Information

Name:	PARI Respiratory Equipment, Inc.
Address:	2412 Pari Way Midlothian, VA 23112
Phone:	(804) 253-7274, ext. 269
Fax:	(804) 253-0260
Contact Name:	Michael Judge
Email:	mike.judge@pari.com

2. Device Name

Name of Device:	eRapid NCP Nebulizer System
Common Name:	Nebulizer
Classification Name:	Nebulizer (21 CFR 868.5630)
Regulatory Class:	II
Product Code:	CAF

3. Legally Marketed Predicate Device

eRapid Nebulizer System, K112859

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

4. Device Description

Both the eRapid NCP and the predicate eRapid device are identical in purpose, function, core technology and method of operation. They are single-patient use, reusable electronic nebulizers, using micro-perforated vibrating membrane technology to aerosolize liquid medications. They are for adult and pediatric inhalation therapy in a home care, nursing home, sub-acute institution, or hospital environment. The devices are hand-held and portable, consisting of a controller and a nebulizer handset, connected with a connection cord. Power input for both devices is provided by either AA batteries, or a DC or AC adapter. Alternate power cords, plugs and adapters allow their use in any country.

5. Mechanism of Action

The medication is filled into the medication reservoir of the nebulizer handset for presenting its liquid content to the vibrating membrane of the nebulizer to generate aerosol for inhalation. There is only the On/Off button on the controller to turn on the device, and start the treatment. When the treatment is done the device automatically shuts off.

This eFlow technology uses a wafer-thin plate or membrane of stainless steel, which is perforated with numerous laser-drilled holes (***Figure 3***). The size of the membrane holes determines the aerosol particle size. There is no other mechanism in place that changes the aerosol particle size, whether through software and/or user interface. This micro-perforated membrane vibrates at a high frequency against a body of fluid. The vibration source is the piezoelectric actuator that is activated by an electronic drive circuit of the Controller. The actuator and the perforated membrane are the main components of the aerosol head that is in contact

with the liquid medication to be aerosolized. Liquid jets are created as an inertial response to the vibration of the membrane. Surface tension and hydrodynamic effects then cause these jets to disperse to produce a stream of precisely controlled droplets.

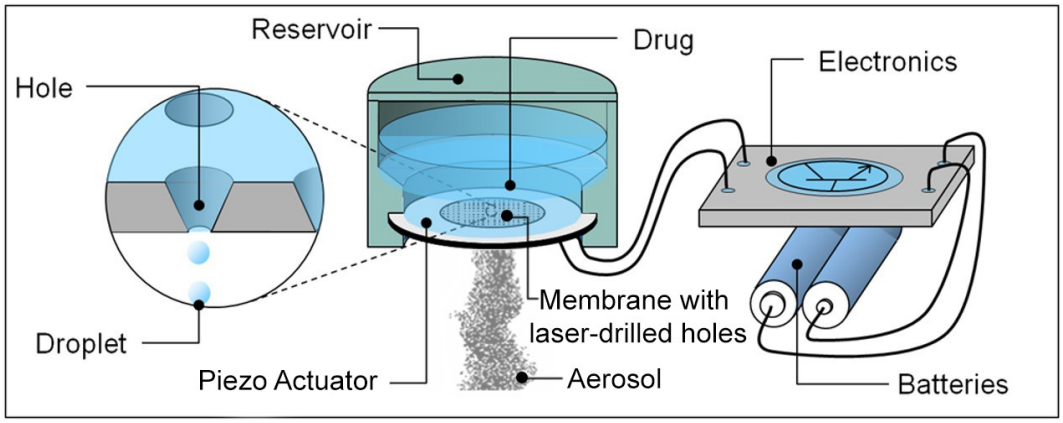

Figure 3: Principle of function of the vibrating membrane technology for aerosol generation

6. Indication for Use

The eRapid NCP Nebulizer System is to be used with patients for whom doctors have prescribed medicine for nebulization. It is intended for adult and pediatric patients age 4 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.

7. Comparison of eRapid NCP Nebulizer system to the Predicate Device

PRODUCT	FDA-Cleared eRapid Nebulizer System	eRapid NCP Nebulizer System
Device Classification	Nebulizer 21 CFR 868.5630	Nebulizer 21 CFR 868.5630
510k No.	K112859	K223840
Manufacturer (Reg. No.)	PARI Respiratory Equipment, Inc. (2954963)	PARI Respiratory Equipment, Inc. (2954963)
Regulatory Class	II	II
Product Code	CAF	CAF
Intended Use / Indications for Use	The eRapid Nebulizer is a handheld nebulizer designed to aerosolize any medications prescribed by a physician. The eRapid Nebulizer System is intended for adult and pediatric patients, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions, and home environments.	The eRapid NCP Nebulizer System is to be used with patients for whom doctors have prescribed medicine for nebulization. It is intended for adult and pediatric patients age 4 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.
Prescription Use	Rx Only	Rx Only

METHOD OF OPERATION		
Technology Used	Micro-perforated vibrating membrane technology to aerosolize liquid medications	Micro-perforated vibrating membrane technology to aerosolize liquid medications
Aerosol Direction/ Output	Sprayed into aerosol chamber, cleared by inspiratory flow	Sprayed into aerosol chamber, cleared by inspiratory flow
Breath Enhanced/ Controlled/ Triggered	Breath enhanced two-way valve system.	Breath enhanced two-way valve system.
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	Remote (tethered) only.	Remote (tethered) only.
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.
DESIGN CAPACITIES		
Medication Reservoir		
Min. Fill	2.0 mL	2.0 mL
Max. Fill	6.0 mL	6.0 mL
Residue	Approx. 1.0 ml residue (depending on filled volume)	Approx. 1.0 ml residue (depending on filled volume)
AEROSOL PERFORMANCE		
Total Output Rate (mg/min)	619 (AVG) SD=72	663 (AVG) SD=60
Mass Median Diameter (µm)	4.35 (AVG) SD=0.09	4.37 (AVG SD=0.10
Geometrical Standard Deviation	1.53	1.53
Fine Particle Fraction <5 (%)	63.56	63.15
ELECTRICAL COMPARISON (eBase Controller)		
	eBase (Round) 1st Generation	eBase (NCP) 2nd Generation
Mean Frequency (Hz)	117040	117650
Mean Power (Watts)	1.255	1.253
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.	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.
Audio-Visual Signals	LED, tone sounds, and illuminated display showing graphical symbols concerning battery level, operational status and failure mode.	Tone sounds, and illuminated display showing graphical symbols concerning battery level, operational status and failure mode.
ELECTRICAL CONECTION		
CISPR 11 Group	II ⧈	II ⧈
CISPR 11 Class	B 🚹	B 🚹
Protection Class	B–with power supply. Internally powered – with batteries	B–with power supply. Internally powered – with batteries
Liquid Protection Rating (controller)	IPX0 (No Protection)	IP22
Rated Supply Voltage (controller)	12V	5V
Rated Input Current (controller)	300 mA	750 mA
Rated Input Power (Controller)	3.6 W	3.75 W
Electrical Requirement (power supply)	100V – 240V, 50 Hz/60 Hz	100V – 240V, 50 Hz/60 Hz
Battery Operation	Four AA disposable or rechargeable batteries	Three NiMH AA rechargeable battery pack
Frequency power for vibrating mesh membrane	1.8w, 117 kHz	1.8w, 117 kHz
NEBULIZER MATERIALS		
Mouthpiece	Polypropylene	Polypropylene
Valve(s)	Silicone rubber	Silicone rubber
Aerosol chamber	Polypropylene	Polypropylene
Fluid feed	Polypropylene, Thermoplastic elastomer	Polypropylene, Thermoplastic elastomer
Aerosol Head	Stainless steel, ceramics, adhesive	Stainless steel, ceramics, adhesive
Headmount	Polypropylene, stainless steel	Polypropylene, stainless steel

Medication Reservoir	Polypropylene, Thermoplastic elastomer	Polypropylene, Thermoplastic elastomer
Medication Cover	Polypropylene, POM, Thermoplastic elastomer	Polypropylene, POM, Thermoplastic elastomer
MECHANICAL		
Weight Controller, Nebulizer Handset, w/Batteries	Approx. 9.5 oz. (269g)	Approx. 9.3 oz. (264g)
Dimensions Controller Handset	 H 43.5 mm Ø 117 mm L 145 x W 50 x H 63 mm	 L 157mm x W 66mm x H 22mm L 145 x W 50 x H 63 mm
Temperature Range	59° to 95°F (15° – 35°C)	59° to 95°F (15° – 35°C)
Humidity	30% to 95%	30% to 95%
Ambient Temperature	- 4° to 140°F (-25° – 70°C)	- 4° to 140°F (-25° – 70°C)
Ambient Humidity	10% to 95%	10% to 95%
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)
Cleaning Aid	PP/TPE accessory to mechanically rinse the aerosol head membrane pores by means of backwashing (back flushing).	PP/TPE accessory to mechanically rinse the aerosol head membrane pores by means of backwashing (back flushing).

a. eRapid NCP Nebulizer System and Predicate eRapid Nebulizer system

Similarities are that both the eRapid NCP 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, microperforated 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, batteries.

Both the eRapid NCP 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, continuous 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.

The difference between the two devices are a 2nd generation eBase controller. The redesigned eBase Controller features: (1) Different housing design with a more modern user interface, (2) Integrated rechargeable battery pack, (3) Higher resolution LCD display, (4)

Adjustable settings for audio and visual features. In addition, The eBase NCP Controller will require a new Connection Cord and Power Supply.

Only the part of the Connection Cord that plugs into the eBase NCP Controller was modified. The other end of the Connection Cord, which is already part of the FDA-cleared device, has not been changed.

Differences from FDA-cleared device are thus confined to the new control unit, connection cord, and power supply.

8. Performance Data

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

a. Biocompatibility and Airpath Testing

The eRapid NCP Nebulizer System uses the identical eRapid Nebulizer Handset that was previously cleared in the predicate eRapid Nebulizer System. All materials used are identical in both formulation and processing, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The three new components proposed in the eRapid NCP Nebulizer System, eBase Controller (1), Connection Cord (2), and AC Power Supply (3), have been evaluated for biocompatibility.

The following common materials were used. Controller (Housing): ABS, TPE, Connection Cord: PP, TPE, and AC Power Supply (Housing): PC.

b. Electromagnetic Compatibility (EMC) and Electrical Safety

EMC testing and Electrical Safety testing were conducted regarding the 2nd generation eBase controller, connection cord and AC power supply. These components were evaluated as a complete eRapid NCP Nebulizer System:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/ (R)2012 and A2:2010/(R)2012
- IEC 60601-1-2:2014 (+AMD1:2020)
- IEC 60601-1-6:2010, AMD1:2013, AMD2:2020
- IEC 60601-1-11:2015/AMD1:2020

c. Software Verification and Validation Testing

The software for this device is of a “moderate level of concern” and validation testing was conducted in accordance with FDA’s guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 2005” Software safety classification is Class B, according to recognized standard IEC 62304.

d. Aerosol Performance

When considering aerosol performance, the eRapid NCP Nebulizer is substantially equivalent to the predicate eRapid Nebulizer. The handset, including the aerosol head, is solely responsible for aerosol performance and is the same handset as used in the predicate eRapid Nebulizer System.

The only variable in the eFlow technology that allows for a change to the aerosol performance is the Nebulizer Handset, and specifically the dimension of the laser drilled holes in the vibrating mesh contained in the Aerosol Head. By increasing or decreasing the size of these laser drilled holes, the aerosol particle size is increased or decreased, respectively. The aerosol particle size is not controlled or changed electronically or with software.

The difference between the predicate and subject nebulizer system is the 2nd generation eBase controller. As stated above the controller does not affect the aerosol performance and only provides a fixed power and frequency to the Nebulizer Handset. Both controllers have been electrically tested to demonstrate they produce the same frequency and power, within the accepted tolerance.

To further substantiate that the two controllers produce the same result, aerosol performance testing was done, and the results compared with the predicate device. The results were similar within the acceptable tolerance limits.

e. Simulated Use Testing

Testing was conducted to determine if the eRapid NCP Nebulizer System performed within specifications stated in the IFU, throughout its useful lifecycle. The testing concluded that the device remained within those specifications

f. Validation of Cleaning and Disinfection Methods

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 on the FDA guidelines, we believe that the eRapid NCP Nebulizer System is substantially equivalent to the previously cleared predicate device.