December 19, 2025

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

Re: K251572
Trade/Device Name: eRapid with eTrack System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: November 24, 2025
Received: November 24, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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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)*
K251572

Device Name
eRapid with eTrack System

Indications for Use *(Describe)*
The eRapid 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
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Contact Name:	Michael Judge
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2. Device Name

Name of Device:	eRapid with eTrack Nebulizer
Common Name:	Nebulizer
510(k) Number:	K223840
Classification Name:	Nebulizer Direct Patient Interface (21 CFR 868.5630)
Regulatory Class:	II
Product Code:	CAF

3. Legally Marketed Predicate Device

Trade/Device Name:	eRapid NCP Nebulizer System
Classification Name:	Nebulizer (Direct Patient Interface)
Proprietary Name:	eRapid NCP Nebulizer System
510(k) Number:	K223840
Regulation No.:	868.5630
Class:	Class II
Panel:	Anesthesiology
Product Code:	CAF

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

4. Reference Device

Trade/Device Name:	AireHealthTM Nebulizer
510(k) Number:	K201167
Regulation Number:	21 CFR 868.5630
Regulation Name:	Nebulizer
Regulatory Class:	Class II
Product Code:	CAF
Dated:	November 2, 2020
Received:	November 3, 2020

5. Device Description

The eRapid with eTrack controller is a single-patient use, reusable electronic nebulizers, using micro-perforated vibrating membrane technology to aerosolize liquid medications. It is 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 is provided by either AA batteries, or a DC or AC adapter. Alternate power cords, plugs and adapters allow their use in any country.

6. 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 selection 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 1***). 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.

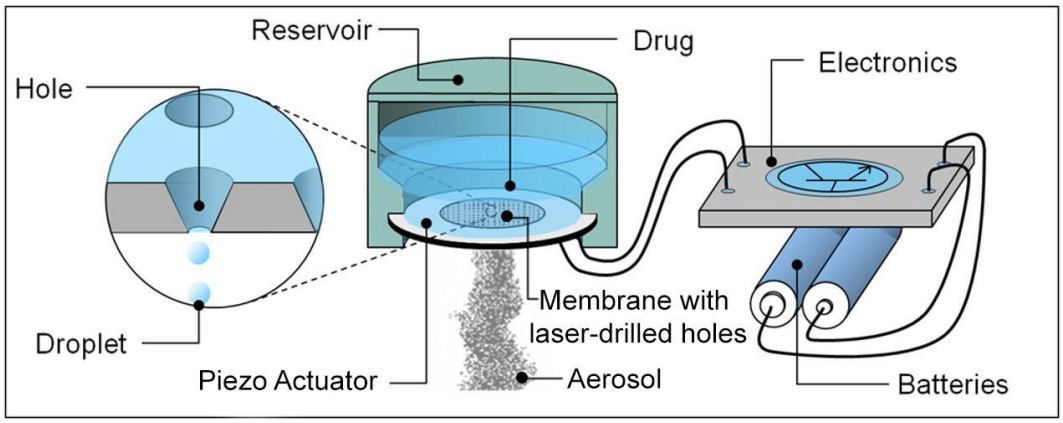

Figure 1: Principle of function of the vibrating membrane technology for aerosol generation

7. Indication for Use

The eRapid with eTrack 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.

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

PRODUCT	FDA-Cleared eRapid NCP Nebulizer System (K223840)	eRapid with eTrack Nebulizer System (K251572)	Comparison
Device Classification	Nebulizer (direct patient interface) 21 CFR 868.5630	Nebulizer (direct patient interface) 21 CFR 868.5630	Identical
510k No.	K223840	K251572	
Manufacturer (Reg. No.)	PARI Respiratory Equipment, Inc.	PARI Respiratory Equipment, Inc.	Identical
Product Code	CAF	CAF	Identical
Intended Use / Indications for Use	The eRapid 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.	The eRapid with eTrack 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.	Identical
Prescription Use	Rx Only	Rx Only	Identical
METHOD OF OPERATION			
Technology Used	Micro-perforated vibrating membrane technology to aerosolize liquid	Micro-perforated vibrating membrane technology to aerosolize liquid	Identical

	medications	medications	
Aerosol Direction/ Output	Sprayed into aerosol chamber, cleared by inspiratory flow	Sprayed into aerosol chamber, cleared by inspiratory flow	Identical
Breath Enhanced/ Controlled/ Triggered	Breath enhanced two-way valve system.	Breath enhanced two-way valve system.	Identical
Fluid Delivery	Direct contact between aerosol head and fluid in sealed chamber (medication reservoir).	Direct contact between aerosol head and fluid in sealed chamber (medication reservoir).	Identical
Generator Configuration	Remote (tethered) only.	Remote (tethered) only.	Identical
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.	Identical

PRODUCT	FDA-Cleared eRapid NCP Nebulizer System (K223840)	eRapid with eTrack Nebulizer System	Comparison
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)	 Identical
AEROSOL PERFORMANCE			
Total Output Rate (mg/min)	663 (AVG) SD=72	650 (AVG) SD=57	Similar
Mass Median Diameter (µm)	4.37 (AVG) SD=0.10	4.36 (AVG) SD=0.08	Similar
Geometrical Standard Deviation	1.53 (AVG) SD=0.02	1.53 (AVG) SD=0.02	Similar
Fine Particle Fraction <5 (%)	63.15	63.47	Similar
ELECTRICAL COMPARISON (Controller Output signal)			
Mean Frequency (Hz)	eBase (NCP) 2nd Generation 117650	eTrack 2nd Generation 117650	Identical

Mean Power (Watts)	1.253	1.253	Identical
SOFTWARE			
Level of Concern	Moderate	Moderate	Identical
Device-Specific	Yes	Yes	Identical
Dependent on External Devices	No	No	Identical
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.	Identical
Audio-Visual Signals	Tone sounds, and illuminated display	Tone sounds, and illuminated display showing graphical	Identical

Wireless Connection	showing graphical symbols concerning battery level, operational status and failure mode. None	symbols concerning battery level, operational status and failure mode. Wi-Fi and Bluetooth	Different Reference K201167 nebulizer with wireless connectivity
PRODUCT	**Predicate** **eRapid NCP Nebulizer System (K223840)**	**eRapid with eTrack Nebulizer System**	**Comparison**
ELECTRICAL CONNECTION			
CISPR 11 Group	1	1	Identical
CISPR 11 Class	B	B	Identical
Protection Class	– with power supply. Internally powered – with batteries	– with power supply. Internally powered – with batteries	Identical
Applied Part Type	BF (nebuliser handset is classified as applied part)	BF (nebuliser handset is classified as applied part)	Identical
Liquid Protection Rating (controller)	IP22	IP22	Identical
Rated Supply Voltage (controller)	5V	5V	Identical
Rated Input Current (controller)	750 mA	750 mA	Identical
Rated Input	3.75 W	3.75 W	Identical

Power (Controller)			
Electrical Requirement (power supply)	100V – 240V, 50 Hz/60 Hz	100V – 240V, 50 Hz/60 Hz	Identical
Battery Operation	Three NiMH AA rechargeable battery pack	Three NiMH AA rechargeable battery pack	Identical
NEBULIZER MATERIALS			
Mouthpiece	Polypropylene	Polypropylene (Bormed)	Identical (Different manufacturer)
Valve(s)	Silicone rubber	Silicone rubber	Identical

a. eRapid with eTrack Nebulizer System and Predicate eRapid NCP Nebulizer system

Both the eRapid with eTrack and the predicate eRapid NCP 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, batteries.

Both the eRapid with eTrack and the predicate eRapid NCP 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 three devices are: 1) The eTrack controller has built in wireless and Bluetooth connectivity modules; 2) The manufacturer of handset material (Polypropylene) is different; 3) The adhesive used to bond the substrate to the piezo was changed to Delo Monopox.

Differences from FDA-cleared device are thus confined to the connectivity feature and the material of the handset.

9. Performance Data

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

a. Biocompatibility and Airpath Testing

The eRapid with eTrack Nebulizer System uses the identical eRapid Nebulizer Handset (except for the manufacturer of material of the handset) that was previously cleared in the predicate eRapid NCP Nebulizer System. All other 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 components proposed in the eRapid with eTrack Nebulizer System, eTrack Controller (1), Connection Cord (2), AC Power Supply (3), and the Handset (4) have been evaluated for biocompatibility.

The following common materials were used. Handset: PP (Bormed HG820MO), Silicone, TPE, Controller (Housing): ABS, TPE, Connection Cord: PP, TPE, and AC Power Supply (Housing): PC. Biocompatibility and Airpath testing was performed on the handset to account for the manufacturer change.

According to the note in ISO 10993-1 chapter 5.2.2 no further biological evaluation is needed, when housings of the device that come in contact with any intact skin, are made from materials in common use.

b. Electromagnetic Compatibility (EMC) and Electrical Safety

EMC testing and Electrical Safety testing were conducted on the eTrack controller, connection cord and AC power supply. These components were evaluated according to following standards:

- 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 with eTrack Nebulizer is substantially equivalent to the predicate eRapid NCP Nebulizer. The handset, including the aerosol head, is solely responsible for aerosol performance and is the same handset as used in the predicate eRapid NCP Nebulizer system (except the manufacturer of the polypropylene material and the adhesive used to bond the piezo to the substrate are different).

The only variable in the eFlow technology that allows for a change to the aerosol performance is the dimension of the laser drilled holes in the vibrating mesh contained in the Aerosol Head. The hole size in the aerosol head determines the particle size of the aerosol. The aerosol particle size is not controlled or changed electronically or with software. Both the predicate and the subject

handset used the same aerosol head, except for the adhesive used to bond the piezo to the substrate. Performance comparison tests were conducted on heads made by the current adhesive (MLT) and the neads made of new adhesive (Delo Monopox). Both the heads performed as per specification and there was no significant difference to suggest that the adhesive change had any effect.

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. The results were similar within the acceptable tolerance limits.

e. Simulated Use Testing

Testing was conducted to determine if the eRapid with eTrack 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.

g. Cybersecurity

A risk assessment was conducted to determine the elements related to cybersecurity and the risks were mitigated to below the level of concern.

h. Wireless Coexistence

An assessment was done to determine how the data transfer was affected in the presence of other wireless equipment.

10. Conclusion

Based on the FDA guidelines and relevant tests, we believe that the eRapid with eTrack Nebulizer System is substantially equivalent to the previously cleared predicate device.