January 23, 2020

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

Re: K191270
Trade/Device Name: Proneb Max
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: December 20, 2019
Received: December 23, 2019

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,

James J. Lee Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K191270

Device Name
Proneb Max

Indications for Use *(Describe)*
The PARI Proneb Max is a tabletop, AC-powered air compressor intended to provide a source of compressed air for use with jet nebulizers with patients for whom doctors have prescribed medication for nebulization. It is intended for adult and pediatric patients 2 years and older, 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.

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."

510(k) Summary: PRONEB MAX – K191270 – PARI Respiratory Equipment, Inc.

1. Submitter

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

2. Device Name

Name of Device:	Proneb Max
Common or Usual Name:	Compressor
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

a. Primary Predicate Device

PARI Vios, K092918, Product Code CAF

b. Reference Device

Proneb Ultra, K002862, Product Code BTI

4. Device Description

The Proneb Max is a tabletop air compressor for use with jet nebulizers, which aerosolize liquid medications for inhalation by patients with respiratory diseases and conditions. The Proneb Max is to be used with adult and pediatric patients ages 2 years and older, and is intended for sale by prescription only. It may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments. It is provided non-sterile.

The Proneb Max compressor creates an airflow that travels to the nebulizer through tubing. The nebulizer is attached to the compressor for its operation. The Proneb Max compressor is constructed of (1) Teflon; (2) ABS; (3) PBT GF30 and, has the following principal internal subcomponents: (1) cylinder/valve system; (2) piston rod/piston sealing; (3) a patient interface (on/off switch); (4) motor 120V/60Hz; (5) power cord/wire harness; and (6) hoses. Energy source for the device is provided by connection to a 120V/60 Hz mains power source.

5. Mechanism of Action

The Proneb Max's mode of action is permanent, i.e., once the on/off switch on the compressor is pressed, the compressor generates compressed air for nebulization until the switch on the compressor is turned off. There is no additional functionality such as a pause function or output adjustment, or auto-shutoff. Nebulization is accomplished as follows: A PARI inhalation system consists of a PARI compressor (such as the subject device), and a PARI nebulizer with mouthpiece or optional accessories, e.g., a mask. The compressor functions as a source of compressed air for the nebulizer. The Proneb Max compressor is powered by a shaded pole, C-frame motor powered by 120V mains via an integrated power cord. This motor drives an oil-free, reciprocating piston pump which draws ambient air in and forces compressed air out of the compressor air outlet for use by a nebulizer cup.

6. Indications for Use

The Proneb Max is a tabletop, AC-powered air compressor intended to provide a source of compressed air for use with jet nebulizers with patients for whom doctors have prescribed medication for nebulization. It is intended for adult and pediatric patients 2 years and older, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.

7. Comparison of Technological Characteristics with the Predicate Device

Table 1. Substantial Equivalence Comparison

PRODUCT	Proneb Max	PARI Vios
DEVICE CLASSIFICATION	CAF, Nebulizer (direct patient interface) 21 CFR 868.5630	CAF, Nebulizer (direct patient interface) 21 CFR 868.5630
510K NO.	K191270	K092918
MANUFACTURER (REG. NO.)	PARI Respiratory Equipment, Inc. (2954963)	PARI Respiratory Equipment, Inc. (2954963)
INDICATIONS FOR USE	The Proneb Max is a tabletop, AC-powered air compressor intended to provide a source of compressed air for use with jet nebulizers. It is intended for adult and pediatric patients 2 years and older, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.	The PARI Vios is a tabletop, AC powered air compressor intended to provide a source of compressed air for use with jet nebulizers. The PARI Vios is intended for adult and pediatric patients for use in hospital, clinic, or home environments.
Environment of use	Home care, nursing home, sub-acute institution, or hospital	Hospital, Clinic, or home environments
Target Population	Adult and pediatric patients 2 years and older	Adult and pediatric patients
Prescription Use	Rx Only	Rx Only
METHOD OF OPERATION		
Technology Used	Piston-driven, oil-free, reciprocating air compressor. AC powered, shaded pole motor, polymer cylinder, Teflon piston seal, ABS housing.	Piston-driven, oil-free, reciprocating air compressor. AC powered, shaded pole motor, polymer cylinder, Teflon piston seal, ABS housing.
Function	Provision of compressed air for use with jet nebulizers.	Provision of compressed air for use with jet nebulizers.
PERFORMANCE		

	Proneb Max / LC Plus			Proneb Ultra / LC Plus		
Mean values	Atrovent	Sultanol	Pulmicort	Atrovent	Sultanol	Pulmicort
MMAD (µm)	4.1	4.0	6.1	4.1	3.8	6.0
GSD (µm)	2.2	2.2	1.8	2.2	2.2	1.8
Fine Particle Fraction (%)	58	59	35	58	61	36
Fine Particle Dose (µg)	121	712	122	125	710	127

PRODUCT	Proneb Max	PARI Vios
ELECTRICAL RATINGS		
Power Wattage	98 W, under normal load	80 W, under normal load
AC Power Supply Input	120 VAC / 60 Hz	120 VAC / 60 Hz
Classification According To IEC 60601-1		
Type of electric shock protection	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 21	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
MECHANICAL		
Dimensions Compressor (L/W/H)	7.28 x 5.1 x 5.9 in	6.5 x 6.5 x 3.75 in.
Weight (approx.)	3.74 lb.	3 lb.
STERILIZATION		
	Does not require sterilization and is not shipped as a sterile product	Does not require sterilization and is not shipped as a sterile product

a. Proneb Max and Primary Predicate PARI Vios

The Proneb Max and primary predicate PARI Vios are identical in purpose, function, core technology and energy source. That is, they are portable, reusable, single-patient use, compressors that generate compressed air for jet nebulizers to aerosolize liquid medications. They are to be used with adult and pediatric patients for whom doctors have prescribed medication, i.e. they are for prescription use only. Note that the patient population is more clearly defined for the subject device. Energy source for the devices are provided by a connection to a mains power source, via power cord.

The Proneb Max and the PARI Vios are technologically equivalent for the following reasons; (1) the performance of the jet nebulizer is dependent on the volumetric flow rate of the jet nozzle generated by the compressor. (2) The Proneb Max and PARI Vios have similar design and construction which consists of a 2-way valve, plastic cylinder, piston with Teflon seal, and an AC-powered shaded pole motor with mounting frame, all contained within an ABS housing. The technology and construction of the subject and predicate devices have no significant differences.

b. Proneb Max and Proneb Ultra Reference Device

The Proneb Max is intended to be PARI's successor product to its Proneb Ultra, currently branded as Vios Pro. Because Proneb Ultra was cleared under Product Code BTI, in this submission Proneb Ultra is listed as a reference device. Performance testing was conducted, comparing Proneb Ultra to the subject Proneb

Max in support of the substantial equivalence claim. The Proneb Max and Proneb Ultra reference device are both piston compressors with similar stroke volume and cycle frequency. (4) The Proneb Max and the Proneb Ultra are made of similar component materials and are driven by shaded pole motors of equivalent size and power range. Both the Proneb Max and the Proneb Ultra have identical compressor performance and intended usage.

8. Performance Data

a. Gas Path Testing

The emitted air quality of the Proneb Max 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) *ISO 18562-3*, Volatile Organic Compounds Analysis*
4) *ISO 18562-2, EPA PM 2.5*, Particular Matter Analysis

*Note that VOC testing demonstrated emitted air quality using worst-case flow rates. The Proneb Max subject device met all acceptance criteria of the test.
All air quality tests concluded that the subject device meets applicable standards.

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

Electrical safety and EMC testing were conducted on the Proneb Max compressor. Testing establishes that, with respect to electrical safety, the Proneb Max meets the applicable requirements of: *(1) IEC 60601-1; (2) IEC 60601-1-2; (3) IEC 60601-1-6; (4) IEC 60601-1-11;and (5) IEC 62366*.

NONCLINICAL PERFORMANCE TESTING

Aerosol Characterization in accordance with *FDA Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators* and *USP <1601>*, as well as simulated use and mechanical testing was conducted as described below to demonstrate substantial equivalence.

c. Aerosol Characterization

Aerosol characterization (particle size distribution) by Next Generation Impactor was performed with the Proneb Max and the Proneb Ultra reference device, using PARI jet nebulizer cups. With respect to aerosol performance, with PARI jet nebulizer cups, the Proneb Max's:
-MMAD (Mass Median Aerodynamic Diameter) is statistically equivalent to that of reference Proneb Ultra;
-GSD (Geometric Standard Deviation) is statistically equivalent to that of the reference Proneb Ultra;
-FPF (Fine Particle Fraction) is statistically equivalent to that of the reference Proneb Ultra; and,
-FPD (Fine Particle Dose) is statistically equivalent to that of the reference Proneb Ultra.

d. Simulated Use Test

Testing was conducted to determine if the Proneb Max remained within specification over its stated useful life. The testing concluded that the device remained within the specifications stated in the IFU.

e. Mechanical Testing

1) Packaging Drop Test

A drop test was performed, based on *ASTM D4169 (2016), DC 13, Assurance Level II* to determine that the design and strength of the Proneb Max 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.

9. Conclusion

Based on the indications for use, technological characteristics, and performance of the device, we conclude that the Proneb Max is determined to be substantially equivalent to the predicate.