February 9, 2018

DRW Medical, LLC
% Stephen Gorski
President
Imagenix, Inc.
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K172284
Trade/Device Name: NAPA LP-15 Airway Pressure Monitor
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: Class II
Product Code: CAP
Dated: January 8, 2018
Received: January 10, 2018

Dear Stephen Gorski:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

K172284

Device Name

NAPA LP-15 Airway Pressure Monitor

Indications for Use *(Describe)*

The NAPA LP-15 Airway Pressure Monitor is intended to measure and monitor airway pressure for neonatal patients being treated with positive pressure therapy, including neonatal Continuous Positive Airway Pressure (CPAP) devices (e.g. Bubble CPAP). The device provides audible and visual alarms when the airway pressure falls outside of the user selected high and low alarm limits. The device is intended to be pole mounted for stationary use in hospitals only. For professional use only.

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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510(k) Summary in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Dan(at)wbmedical.com

Contact Person: Mr. Dan Tatum

Position/Title: Managing Director

Date of Preparation: February 9, 2018

(2) **Trade Name: NAPA LP-15 Airway Pressure Monitor**

Common/Classification Name: Monitor, Airway Pressure (Includes Gauge and/Or Alarm);

Regulation: 21 CFR §868.2600

Product Code(s): CAP

Class: Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K992101	Criterion 40 Airway Pressure Monitor	Caradyne Ltd. (now Respironics)

Reason for Submission: New Device

(4) **Description of Device:**

The NAPA LP-15 Airway Pressure Monitor is a compact mains operated monitoring device that continuously monitors and displays the neonatal patient's average airway treatment pressure during neonatal CPAP therapy (e.g. Bubble CPAP) and provides high and low alarms for pressures that exceed set limits.

NAPA LP-15 Airway Pressure Monitor features:

- Device measures, monitors, and continuously displays a two second mean airway pressure from 0.0-15.0 cmH_2O with resolution of 0.1 cmH_2O.
- Manual zero pressure sensor function (zero key).

- User interface provides adjustable audio and visual high and low airway pressure alarms when the mean airway pressure falls outside of the user-selected high and low alarm limits.
- The high alarm settings are from 4.0 to 15 cmH_20.
- Low alarm settings are from 0.1 to 8.0 cmH_2O.
- Alarm Suspend button allows alarm to be silenced for two minutes.
- Mains operated: The device is supplied with a medically rated power adapter.
- Single patient use airway measurement tubing with an integral moisture barrier.
- The NAPA LP-15 Airway Pressure Monitor may be pole mounted with the available pole mount bracket and clamp.

(5) **Intended use:**

The NAPA LP-15 Airway Pressure Monitor provides pressure measurement resolution and alarm adjustment ranges which are tailored to the treatment ranges of neonatal BCPAP treatment (0 – 15 cmH_2O). These allow a clinician to set the alarm thresholds to sense the small drops in pressure that may occur in neonatal CPAP treatment (e.g. Bubble CPAP). The device is specified for professional use in a healthcare facility.

Indications for Use:

The NAPA LP-15 Airway Pressure Monitor is intended to measure and monitor mean airway pressure for neonatal patients being treated with positive pressure therapy, including neonatal Continuous Positive Airway Pressure (CPAP) devices (e.g. Bubble CPAP). The device provides audible and visual alarms when the airway pressure falls outside of the user selected high and low alarm limits. The device is intended to be pole mounted for stationary use in hospitals only. For professional use only.

Prescription device (R_X).

Discussion of Differences in Indications to the Predicate Devices:

The submitted device and referenced predicate devices have the following differences in their indication statements regarding pressure monitoring:

- The specified patient population for the NAPA LP-15 Airway Pressure Monitor is neonatal patients only. The Criterion 40 Airway Pressure Monitor has no specified patient population (i.e. adult through neonatal population possible). The NAPA LP-15 Airway Pressure Monitor claims are within the claimed population of the predicate device.
- The predicate monitor displays peak pressure and real-time airway pressures, the NAPA LP-15 Airway Pressure Monitor only provides an average (mean) CPAP treatment pressure.
- The predicate monitor may be used with positive pressure devices which do not include pressure measurement capabilities, e.g. resuscitation bags or basic ventilators, or as an independent backup pressure monitor for devices with pressure measurement capability. NAPA LP-15 Airway Pressure Monitor only

claims monitoring of positive pressure therapy, including neonatal Continuous Positive Airway Pressure (CPAP) devices (e.g. Bubble CPAP).

The differences in the wording of subject and predicate device indications for use are within the scope of the predicate device for intended use of the subject device as a neonatal airway pressure monitor when used as labeled.

(6) Technological Characteristics:

Both the NAPA LP-15 Airway Pressure Monitor and the Criterion 40 are microprocessor controlled devices for measuring patient airway pressure using the same technological principles. Refer to the following comparison table:

Comparison of Technological Features to Predicate Devices:

Product/Feature	DRW Medical NAPA LP-15 Airway Pressure Monitor	Caradyne Criterion 40 Airway Pressure Monitor	Remark
Manufacturer	DRW Medical LLC	Caradyne Ltd. (now Respironics)	
Model Number(s)	NAPA LP-15	Criterion 40	
510(k) Number	**K172284**	**K992101**	
Intended Use/Application	Measure mean airway pressure for neonatal patients being treated with positive pressure therapy, including neonatal CPAP (e.g. Bubble CPAP).	Measure airway pressure for any patient utilizing positive pressure devices where monitoring is desired	Different, and within the scope of predicate device.
Patient Population	Neonatal patients	(none specified: not limited to specific patient type)	Different, and within the scope of predicate device.
Environment of Care	Hospitals	Hospital, home, and sub-acute institutions; stationary and intra-institution transport	Different, and within the scope of predicate device.
Patient Interface	Disposable single patient use pressure measurement tubing from patient's airway to monitor	Disposable single patient use pressure measurement tubing from patient's airway to monitor	Identical
Alarms	✓ YES	✓ YES	Identical
Measurement principle	Solid state pressure sensor	Solid state pressure sensor	Identical
Control System	Internal microprocessor	Internal microprocessor	Identical
Displayed pressure measurement(s)	Average (Mean) Pressure	Peak Pressure, Real Time Pressure, Average Pressure	Different, and within the scope of predicate device.
Specified pressure measurement range	0 - 15.0 cm H_2O	0 - 99.5 cm H_2O	Different, and within the scope of predicate device.

Product/Feature	DRW Medical NAPA LP-15 Airway Pressure Monitor	Caradyne Criterion 40 Airway Pressure Monitor	Remark
Measurement accuracy	± 0.5 cm H_2O	± 1 + 3% of reading, rounded up to nearest 0.5 cm H_2O	
Displayed pressure resolution	0.1 cm H_2O	0.5 cm H_2O	Different, and within the scope of predicate device.
Low alarm range	0.1 - 8.0 cm H_2O; 0.1 cm H_2O resolution	1 – 20 cm H_2O; 1 cm H_2O resolution	Different, and within the scope of predicate device.
High alarm range	4.0 - 15.0 cm H_2O; 0.1 cm H_2O resolution; 1 cm H_2O resolution > 10 cm H_2O	5 – 99 cm H_2O; 1 cm H_2O resolution	Different, and within the scope of predicate device.
Overall dimensions:	H: 127 mm (5.0 in.) W: 64 mm (2.5 in.) D: 32 mm (1.24 in.)	W: 198 mm H: 94 mm D: 188 mm	
Weight	180 grams (0.4 lb.)	680g	
Pole mount	✓ YES, with offered bracket and clamp	✓ YES, option	
AC Mains Power Adapter Type	Medically rated external plug in power supply: AC Mains input, DC output	External plug in power supply: AC Mains input, DC output	

As summarized above, the NAPA LP-15 Airway Pressure Monitor utilizes equivalent technological characteristics and specifications as the listed predicate devices.

(b) (1) **Non-Clinical Tests Submitted:**

The NAPA LP-15 Airway Pressure Monitor including its DC power adapter was laboratory tested to current applicable standards for medical device electrical safety and electromagnetic compatibility as well as collateral standards for alarms. The following standards were utilized in compliance testing:

- Electrical safety testing per IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-1-2
- Alarms testing per IEC 60601-1-8
- Environmental and mechanical testing per the test levels specified in home healthcare: IEC 60601-1-11; (note informative only: device is not specified for home use)

The monitor met the acceptance criteria for compliance to the standards.

The monitor with accessory tubing was tested for static and pressure measurement accuracy and functional performance with a calibrated reference source.

The monitor met acceptance criteria for pressure accuracy and function.

Risk management, risk and hazard analysis of the monitor/system was performed to the following standard:

- Application of risk management to medical devices per ISO 14971

The monitor met the acceptance criteria for residual risks.

The NAPA LP-15 Airway Pressure Monitor embedded software was developed in accordance with FDA guidelines for MODERATE level of concern devices. The software lifecycle process was evaluated to meet:

- Medical device software lifecycle process per IEC 62304 with software safety class B (equivalent to MODERATE level of concern).

  The device software was verified to requirements and validated to meet the specified intended use(s).

The patient contact materials, a cleared tubing set accessory with contact to the patient airway was evaluated for biocompatibility by reference to the manufacturers technical file.

An accelerated aging test was performed for a simulated aging of 3 years.

The monitor met the acceptance criteria for the accelerated aging test.

In summary, the NAPA LP-15 Airway Pressure Monitor met test criteria for standards conformance to the applicable standards, pressure measurement ad accuracy. Residual risks met criteria for acceptability for the intended use.

(2) Clinical Tests Submitted:

No clinical tests were submitted.

(3) Conclusions from Tests:

As described in (b)(1) and (b)(2) above, the NAPA LP-15 Airway Pressure Monitor is equivalent to the predicate device as supported by compliance, and laboratory testing, and risk management and system level software evaluations as described above in the non-clinical testing, and submitted in Sections 16, 17, and 18 of the device 510(k) submission.

The results of all tests demonstrate that the reusable NAPA LP-15 Airway Pressure Monitor is substantially equivalent to the referenced predicate device.