December 15, 2022

Dynasthetics LLC
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K220591
Trade/Device Name: Proxima
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: NFB
Dated: November 11, 2022
Received: November 14, 2022

Dear Paul Dryden:

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 -S

James J. Lee, Ph.D.
Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220591

Device Name
Proxima

Indications for Use *(Describe)*
The Proxima is intended for prescription use only, to be used for adult patients that require supplemental oxygen in a hospital setting.

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

Date Prepared: 15-Dec-22

Sponsor:
Dynasthetics LLC
3487 West 2100 South #300
Salt Lake City, UT 84119
Tel - 801-484-3820

Official Contact: Joseph Orr
President, Dynasthetics, LLC

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name:	Proxima™ Model-100 Smart Supplemental Oxygen System
Common/Usual Name:	Oxygen Conserver
Classification CFR:	21 CFR 868.5905
Classification Code:	NFB
Classification Name:	Conserver, Oxygen

Predicate Device:	Inovo Evolution Electronic Oxygen Conserver, K113111
Proprietary or Trade Name:	Proxima™ Model-100 Smart Supplemental Oxygen System
Common/Usual Name:	Oxygen Conserver
Classification CFR:	21 CFR 868.5905
Classification Code:	NFB
Classification Name:	Conserver, Oxygen

Device Description:
The Proxima Model-100 is an electronic oxygen conserving device designed for use in a hospital environment. It incorporates a sensitive pressure sensor to detect inhalation, an electronic valve to deliver precise volume of oxygen and a graphical touch screen interface. In pulsed mode the Proxima delivers flows equivalent to 1 to 15 liters per minute of continuous oxygen flow. The volume of each bolus is calculated such that the patient receives the equivalent of the set volume regardless of how slow their breath rate is. To make sure the patient receives oxygen, even if inhalation is not detected, the Proxima automatically changes from pulsed to continuous oxygen flow at the set flow rate if inhalation is not detected for 15 seconds. Proxima displays a warning message to indicate low battery, low oxygen supply pressure, dislodged cannula, lack of inhalation and low nasal airflow. The Proxima is powered using an external 9-volt DC power supply and includes an internal back-up battery. The Proxima is for use with a customer supplied, dual lumen demand nasal cannula, for example the Salter Labs 4807 or similar, to ensure proper patient usage.

Indications for Use:
The Proxima is intended for prescription use only, to be used for adult patients that require supplemental oxygen in a hospital setting.

We present the proposed device vs. the predicate in table below.

Table of Comparison and Differences

The table below outlines the features of the Dynasthetics Proxima and compares it to the predicate device to establish substantial equivalence.

Attribute	Subject Device	Predicate Device	Comments
Device Name	Proxima™ Oxygen Delivery System	Chad Therapeutic Evolution Electronic Oxygen Conserver	
Model	100	OM-900	
510(k) Number	K220591	K113111	
Device classification and Product Code	NFB 868.5905	NFB 868.5905	
Indications for use	The Proxima is intended for prescription use only, to be used for adult patients that require supplemental oxygen in a hospital setting.	The Inovo Evolution Motion is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 7 liters per minute, in their home and for ambulatory use.	Similar The indications for use are similar for the subject and predicate devices. Both provide an option for continuous flow oxygen delivery and bolus inspiration only mode. The predicate device is designed to be used in a hospital or at the patient's home. The subject device is designed to be used in a hospital setting only by trained professionals.
Patient population	Any adult patient for whom supplemental oxygen is indicated	Any patient for whom up to 6 L/min of oxygen has been prescribed	Similar
Environment for use	Hospital setting	For hospital, home and ambulatory use	Subject device is only for use in a hospital setting
Contraindications	NOT INTENDED to be life sustaining or life supporting. NOT INTENDED for use in patients who cannot maintain a patent airway NOT INTENDED for applications requiring less than 1 L/min of supplemental oxygen NOT INTENDED for home use	Not to be used for life support applications. In addition, it is not intended for use by patients who breathe more than 40 breaths per minute or who consistently fail to trigger the device. It is not to be used while asleep.	Similar The predicate and the subject device both state that the devices should not be used as life support devices. Subject device is not intended for home use.
Constant oxygen flow mode	1-15 L/pm	Continuous flow of 2 L/pm ± 0.5 L/pm	Similar
Pulsed oxygen mode	1, 2, 4, 6 10 and 15 L/min equivalent oxygen flow Volume of oxygen pulses are selected to equal 40% of the set oxygen flow over one minute. Pulse volumes are adjusted according to the set oxygen flow rate and the time since the previous pulse.	1, 2, 3, 4, 5, 6 L/min equivalent oxygen flow	Subject device has the option to deliver higher oxygen flow rates

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Attribute	Subject Device	Predicate Device	Comments
Pulse accuracy	Greater of 3 mL or ±10% of the nominal bolus volume	Not specified	Pulse volume accuracy is similar
Continuous flow settings	1, 2, 4, 6, 10 and 15 L/min	2 L/min	Similar Subject has more continuous flow settings than predicate
Continuous flow accuracy	The greater of ±0.25 l/min or ±10% of the set flow rate for flows between 1 and 15 L/min	N/A	Flow rate accuracy of the subject device is similar to that of the predicate device
Oxygen Savings ratio	2.5:1 regardless of breath rate	2.5:1 to 5.0:1 depending on breath rate	Similar
Initiation of Bolus	At onset of inhalation	At onset of inhalation	Similar
Oxygen Bolus Size	Variable	Variable	Similar
Automatic bolus size adjustment?	Yes	Yes	Similar
Oxygen Bolus Volume by setting at 20 breaths/min	Setting 1: 20 mL	Setting 1: 10-15 mL	Similar
	Setting 2: 40 mL	Setting 2: 20-25 mL	
	---	Setting 3: 30-35 mL	
	Setting 4: 80 mL	Setting 4: 40-50 mL	
	---	Setting 5: 50-60 mL	
	Setting 6: 160 mL	Setting 6: 60-75 mL	
	---	Setting 7: 70-80 mL	
	Setting 10: 320 mL	---	
	Setting 15: 400 mL	---	
Maximum bolus volume	425 mL	75 mL	A larger bolus volume allows for a broader range of patients
Breathing frequency	Up to 40 breaths per minute	Up to 40 breaths per minute	Similar
Microprocessor controlled	Yes	Yes	Similar
Oxygen Flow control	Electronically controlled valve	Electronically controlled valve	Similar
Breath trigger detection method	Electronic pressure sensor	Electronic pressure sensor	Similar
Oxygen cannula	Any standard, dual-lumen demand nasal cannula, for example the Salter Labs 4807 or similar.	Any single lumen oxygen cannula	Overall function and performance are similar
Alarms indicators?	Yes	Yes	Similar
User interface	Touch screen button and slider	Touch button and rotary knob	Similar
Displayed parameters	Set oxygen flow rate Breath rate (Synchronized breath mode)	Set oxygen flow rate	Similar

510(k) Summary

Attribute	Subject Device	Predicate Device	Comments
Option for continuous flow when breaths not detected	Yes, automatic If inhalation is not detected after 15 seconds, mandatory continuous flow is automatically given at the set flow rate	Yes, manual	Similar
Gas source	Regulated low pressure hospital oxygen supply (50-55 PSI)	High-pressure unregulated oxygen cylinders (200 to 3000 PSI)	Similar
Trigger Method	Negative inspiratory effort from patient inhalation	Negative inspiratory effort from patient inhalation	Similar
Trigger sensitivity	0.05 cm H2O	0.5 cm H2O	The subject device requires less pressure drop to trigger breaths
Peak pulse oxygen flow	30 L/min	Unspecified	Similar
Continuous flow settings	0, 1, 2, 4, 6, 10 and 15 L/min	2 L/min	Similar
Keypad	On/off button, Capacitive touch screen	Rest and active buttons, pulse volume selector	Similar function different technology
Housing	Injection molded plastic enclosure	Injection molded plastic enclosure	Similar
Pre-valve manifold material	Machined aluminum	Brass	Similar
Integral pressure regulator	None	Brass C36000 high-pressure components	Similar
Oxygen pressure gauge	None	0-300 PSI	Similar
Primary power source	Low DC voltage external double insulated medical grade power adapter	2 “AA” disposable/rechargeable batteries (user changeable)	Similar Both the subject and predicate devices can be operated using battery power. The subject device is designed to be operated using an external DC power supply
Battery	Internal IEC 62133 certified rechargeable backup battery (not user changeable)	2 “AA” disposable/rechargeable batteries	Both the subject and predicate can operate on battery power.
Battery life	Backup battery life > 30 minutes	2 years	Battery life is different since the subject device is limited to hospital settings, the length of backup battery power is less critical. Subject device battery is backup only (non-primary power source)

Substantial Equivalence Discussion

As described in the table above the Proxima is viewed as substantially equivalent to the predicate device because:

Indications –

- The intended therapeutic use of the predicate and subject devices are similar:
- **Discussion** – both the subject and predicate devices provide supplemental oxygen therapy to patients. Both the subject and predicate devices are intended for use by healthcare providers to administer supplemental oxygen to patients. The subject device is intended to be used only for adult patients in a hospital environment and both are to be used for patients requiring supplemental oxygen.

Environment of Use –

- The subject and predicate devices both include hospital environments.

Discussion – The predicate device includes home and ambulatory use, this does not impact substantial equivalence

Technology –

- The technological principles of delivering oxygen in a pulsed dose to the patient by sensing inhalation. Oxygen is delivered via nasal cannula to the nostrils.

Discussion – The devices are the similar.

Non-clinical Testing Summary -

Biocompatibility

The Proxima Oxygen Conserver has several component which have patient contact. According to ISO 10993-1 and ISO 18562-1 for the materials in patient contact. They are:

- Main unit
    - Dry gas pathway
    - Externally Communicating, Tissue
    - Duration of use is permanent (>30 days).

Testing included:

- ISO 18562-2 – PM
- ISO 18562-3 – VOCs

Discussion – Testing has shown that particulate and VOC emissions do not create a significant risk to patients.

Electrical, EMC, EMI testing

- We have evaluated the proposed device per ANSI/AAMI/ES 60601-1, IEC 60601-1-2, AIM Standard 7351731, IEC 60601-1-8 and ISO 80601-2-67 the device performed as intended and met the requirements.
- **Discussion –** The proposed device met the requirements of the standards and is considered safe.

Bench testing –

- Bench testing was performed to verify the performance to specifications of the proposed device. Testing included:

- ISO 80601-2-67:2020 - Medical Electrical Equipment - Part 2-67: Particular Requirements For Basic Safety And Essential Performance Of Oxygen-Conserving Equipment
    - Pulse Volume
    - Breath Rate
    - Oxygen Delivery
    - Continuous Flow
    - Leak Compensation
    - Breath Trigger Pressure
- Fire Propagation
- Cleaning Durability

Discussion – The proposed device was tested to assure that it meets performance specifications. Upon completion of the tests, it was found to meet its performance requirements.

Discussion of Differences

There are no significant differences in critical function between the proposed device and the predicate device. Differences are discussed in **Table** above.

The performance testing has demonstrated that the subject device met the applicable standard performance requirements. We have not identified any new or different risks compared to the predicate in the comparative table or risk analysis.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.