November 14, 2020

Incoba Ltd. d/b/a Dynaris
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K200401
Trade/Device Name: Apogee
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NFB
Dated: October 19, 2020
Received: October 20, 2020

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,

Todd Courtney
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 on last page.

510(k) Number *(if known)*

K200401

Device Name

Apogee

Indications for Use *(Describe)*

The Apogee is a gas conserver intended as a delivery device for medical grade oxygen from a high-pressure oxygen cylinders. Apogee is an ambulatory device which allows patients to ambulate longer than they would with continuous flow regulator on the same cylinder. The Apogee is intended to be used in the hospital, healthcare facilities, or home care 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.

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Date Prepared: 13-Nov-2020

I Submitter

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Sponsor Contact: Lon Aylsworth, CEO

Submission Correspondent: Paul Dryden
ProMedic, LLC

II Device

Proprietary or Trade Name:	**Apogee**
Common/Usual Name:	Oxygen Conserver
Classification Name:	Oxygen Conserver (21 CFR 868.5905)
Regulatory Class:	II
Product Code:	NFB

III Predicate Device: K090421 – Inspired Technologies Model 350G

IV Device Description:

The proposed device, Apogee, senses each nostril independently through a bifurcated cannula and responds to the dynamic changes in nasal air-flow making a breath-to-breath determination of where to deliver the next bolus of oxygen: to the left, the right, or both nostrils.

The Apogee Device is composed of the main components as detailed below:

- Control Unit
  The control unit will house the main control electronics and interface ports that are needed to perform oxygen conservation. The main components of the control unit are: AA batteries, main control board with an embedded processor, ON/Off switch, cannula interface tube and oxygen regulator.
- Control Board (Regulated Voltage Supply)
  The control board contains a microprocessor and circuitry to take the input voltages from three (3) AA batteries to provide all the regulated voltages for the Apogee Device.
- Embedded Processor
  The embedded processor is the master controller of the Apogee Device.
- User supplied Demand Cannula
  The user supplies a standard bifurcated nasal cannula.
- The Apogee Bypass Cannula and Restrictor and Cylinder Tubing
  - The Apogee Bypass Cannula is to be used in a Continuous mode and connects to one end of the Apogee Bypass Cannula restrictor.

V Indications for Use:

The Apogee is a gas conserver intended as a delivery device for medical grade oxygen from a high-pressure oxygen cylinders. Apogee is an ambulatory device which allows patients to ambulate longer than they would with continuous flow regulator on the same cylinder. The Apogee is intended to be used in the hospital, healthcare facilities, or home care environments.

VI Comparison of Technological Characteristics and Performance with the Predicate

Table 1 is a comparison – Subject Device vs. the Predicate including technological characteristics and performance.

Table 1 - Table of the Similarities and Differences of Predicate vs. Proposed Device

	Proposed Apogee	**Predicate Inspired Technologies Model 350G – K090421**	**Comments**
Product Classification	NFB - conserver, oxygen Regulation Description - Noncontinuous ventilator (IPPB) CFR 868.5905	NFB - conserver, oxygen Regulation Description - Noncontinuous ventilator (IPPB) CFR 868.5905	Similar
Indications for Use	The Apogee is a gas conserver intended as a delivery device for medical grade oxygen from a high-pressure oxygen cylinders. Apogee is an ambulatory device which allows patients to ambulate longer than they would with continuous flow regulator on the same cylinder. The Apogee is intended to be used in the hospital, healthcare facilities, or home care environments.	The Inspired Technologies 350G Gas Conserver is intended as a delivery medial-grade device for oxygen from high-pressure oxygen cylinders. This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder. The 350G Gas Conserver is intended to be used in the hospital, healthcare facilities, or home care environments.	Similar
Environments of use	Hospital, healthcare facilities, or home care environments	Hospital, healthcare facilities, or home care environments	Similar
Population	Patients that require supplemental oxygen	Patients that require supplemental oxygen	
Prescriptive	Yes	Yes	Similar
Technology and Principle of Operation	Delivers oxygen in a pulsed dose to the patient by sensing inhalation. Delivers oxygen via a user supplied nasal cannula to either nostril Uses 2 pressure sensors	Delivers oxygen in a pulsed dose to the patient by sensing inhalation. Delivers oxygen via nasal cannula to both nostril Uses 2 pressure sensors	Similar technology Different in delivery to the nostrils but includes the use of 2 sensors for detecting the start of a breath
Patient Oxygen Outlet Pressure	19-30 psig	19-25 psig	Similar
Software driven	Yes	Yes	Similar

	Proposed **Apogee**	**Predicate** **Inspired Technologies** **Model 350G – K090421**	**Comments**
Dosing algorithm and number of settings	16 cc/lpm (accuracy not provided) Setting (lpm) 1, 1.5, 2, 2.5, 3, 4, 5, 6	16 cc/lpm (accuracy not provided) Setting (lpm) 1, 1.5, 2, 2.5, 3, 4, 5, 6 Sport modes	Similar dosing algorithm Similar range of settings Subject device does not have sport mode
Back-up mode	Continuous flow in by-pass – 3 Lpm	Continuous flow - 2 Lpm	Both have means for back-up mode
Power source	3 – "AA"	4 – "AA"	Similar
Status Indicators	Device "on" Low battery No flow Audible beeps	Device "on" patient setting-valve activation Battery status No audible alarms	
Breath sensing	< -0.3 cmH_2O	+0.03 to -0.2 cmH_2O	Similar
Breath range	Up to 40 BPM	Up to 35 BPM	Similar
Patient interface	User supplied bifurcated nasal cannula Delivers oxygen to one nostril	Nasal Cannula Delivers oxygen to both nostrils	Similar
Operating conditions	5°C to 40°C RH 15-90% Atm Pressure range – 700 to 1060 hPa	N/A	Apogee complies with Home healthcare environment requirements per IEC 60601-1-11ed 2
Size (LxWxH) mm	Size – 146 x 72.3 x 39 mm Weight – 321 grams	Size - 152.4 x 101.6 x 88.9 mm Weight – 630.5 grams	Apogee is smaller in size
Water Ingress	IP22	IPX1	Improved liquid Ingress capability. No differences of safety or effectiveness.
Accessories	User supplied Nasal cannula, single patient, multi-use	Nasal cannula, single patient, multi-use	Similar
Performance	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-67	Not applicable	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-67
Biocompatibility	Externally communicating, Tissue Duration – permanent ISO 18562-2, 18562-3	Externally communicating, Tissue Duration – permanent	Similar

VII Performance Data

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

Biocompatibility – The materials in patient contact are considered Externally communicating / Tissue Permanent duration of use. The testing included:

- Gas emission VOC
- Particulate Matter (PM2.5)
- Inorganic gases – CO, CO_2 and Ozone
- Toxicological Risk Assessment

Electrical Safety and EMC
Electrical safety and EMC testing were conducted on the subject device. The system complies with AAMI ANSI ES 60601-1: 2005 + A1: 2012 and IEC 60601-1-11 standards for safety and IEC 60601-1-2: 2014 for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted. The software for this device was considered as a "moderate" level of concern.

Mechanical, Animal, and Clinical Testing
Testing related to storage, effects of aging, drop and durability were performed. There were no animal or clinical testing was performed.

Bench Testing
Bench testing was performed to verify the performance to specifications of the proposed device and the predicate. Testing demonstrated that both devices delivered an equivalent amount of oxygen bolus to the patient in the same time. Testing included: Bolus, Volume Flow, Trigger sensitivity, performance pre- and post-cleaning.

VIII Conclusions

Discussion of Differences –
The proposed device differs from the predicate which delivers the bolus to both nostrils where not all oxygen is entrained to the lungs as one nostril make be restricted. Whereas the subject device delivers the same total size bolus only to the nostril that the pressure sensors senses as patent, delivering the same bolus to the most patent nostril.

Substantial Equivalence Conclusion
The performance testing has demonstrated that the subject devise met the applicable standard performance requirements. The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.