July 24, 2025

Responsive Respiratory
% Paul Dryden
President
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K250322
Trade/Device Name: Respond OC Conserving Regulator (130-0800)
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NFB
Dated: June 22, 2025
Received: June 23, 2025

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 (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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250322

Device Name
Respond OC Conserving Regulator (130-0800)

Indications for Use *(Describe)*
The Respond OC Conserving Regulator (130-0800) is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use. It may also be used to deliver a constant flow of oxygen to the patient.

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.

510(k) Summary

Date Prepared:	22-Jul-25
Sponsor:	Responsive Respiratory, Inc. 6244 Lemay Ferry Rd. Saint Louis, MO 63129 Steve Bannon, President (866) 333-4030
Submission Correspondent:	Paul Dryden - ProMedic, LLC
Proprietary or Trade Name:	Respond OC Conserving Regulator (130-0800)
Classification Name:	Conserver, Oxygen
Product Code:	NFB
CFR	21 CFR 868.5905
Proprietary or Trade Name:	Chad Therapeutics Bonsai Model 800 – K070740
Classification Name:	Conserver, Oxygen
Product Code:	NFB
CFR	21 CFR 868.5905

Device Description
The Respond OC Conserving Regulator (130-0800) is a dual mode high pressure oxygen regulator and conserving device that allows for either a continuous or conserve flow of medical grade oxygen to the patient. The device is designed with a CGA 870 style yoke for use with ambulatory oxygen cylinders. The integrated regulator reduces cylinder pressure to 22psig (+/-3psi) to the sensing diaphragm which allows the Respond OC to sense the start of inhalation by the patient and release a controlled amount of oxygen by pneumatic timing in short bursts into the lungs via an oxygen cannula. The Respond OC supports a delivered oxygen equivalency of 1 to 5 LPM in the conserve mode, which extends the ambulatory time of cylinders up to 6:1 based on the cylinder pressure and selected setting. The continuous flow mode offers settings of 2, 3 and 4 LPM if the patient requires a constant flow of oxygen.

Principle of Operation
The Respond OC Conserving Regulator (130-0800) is a dual mode device allowing for both continuous and conserve flows. Oxygen flow rates are adjusted by setting an external flow control knob to the prescribed rate. In continuous mode, the Respond OC functions as a standard continuous flow regular, similar to traditional click-style regulators. In conserve mode, the unit acts as a conserving device, which increases the ambulatory time over that of continuous flow systems. The flow of oxygen is controlled by the patient's inhalation, which triggers a sensing diaphragm within the control module to release a bolus of oxygen directly into the lungs at the beginning of the inhalation cycle.

Indications for Use:
The Respond OC Conserving Regulator (130-0800) is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use. It may also be used to deliver a constant flow of oxygen to the patient.

Patient Population:
Patients that require supplemental oxygen in their home and for ambulatory use.

Environments of use:
Home and ambulatory use.

Substantial Equivalence Discussion

Indications for Use –
The indications for use for the subject and predicate devices are similar. We have updated the Indications for Use language to mirror more recent submissions.
Discussion – The indications for use between the subject and predicate device are similar.

Technology and construction –
The Respond OC Conserving Regulator (130-0800) is a combination high pressure oxygen regulator and conserving device. The unit operates similarly to other oxygen conservers currently on the market today wherein the device contains a traditional oxygen regulator coupled with a conserver. It is constructed with a CGA 870 yoke for use with high pressure oxygen cylinders and utilizes an aluminum unibody design with brass componentry in the high pressure areas. The device requires no electrical power source. Operating pressure range is 300 – 3000 psig with a nominal outlet pressure of 22 psi.

The device uses a single lumen cannula attached to a single outlet port that delivers oxygen to the patient. In regulator (steady flow) mode, the device features selectable flows of 1-5 LPM equivalence in 1 LPM increments. Flow rates are adjustable by a click-style flow control knob that allows adjustment between both steady flow or conserve flows without having to turn the device or flow of oxygen off. In the conserve mode, the flow of oxygen is triggered and controlled by the patient respiratory cycle. Upon inhalation, the sensing diaphragm within the control module is triggered to release a bolus of oxygen to the patient. No oxygen is delivered during exhalation.

The technology utilized within the device is substantially equivalent to the predicate device – Chad Therapeutics Bonsai. Both units are pneumatic devices designed for use with CGA 870 connections on high pressure oxygen cylinders and are combination devices offering conserve and continuous flow modes of oxygen delivery to the patient. Each device utilizes a click-style knob to select delivery modes and oxygen flow settings. In conserve mode, both devices utilize a sensing diaphragm to sense the inhalation/exhalation cycle and deliver a bolus of oxygen to the patient. Further, both units include similar materials of construction, input operating pressures, outlet pressures, inlet configuration, outlet connection, gauges, inhalation trigger points, oxygen conservation percentages and weight.

The functional differences between the units include body styles and the length of oxygen bolus delivery during inhalation. Since pulse is a fixed time and the breath rate is variable, the percent of the breath that the pulse uses is a function of the breath rate.

- At 15 BPM, the total breath is 4 seconds. With an assumed 1:1 I:E ratio, the inhale time is 2 seconds
- At 20 BPM, the total breath is 3 seconds. With an assumed 1:1 I:E ratio, the inhale time is 1.5 seconds
- At 30 BPM, the total breath is 2 seconds and the same assumed 1:1 I:E ratio, the inhale time decreases to 1 second.
- Using the above examples, the differential between the delivery and length of the bolus fluctuates between .4 second difference at 15 BPM, to less than .2 seconds at 30 BPM.

Discussion – The differences do not raise different questions of safety and effectiveness.

Environment of Use –
The environment of use is identical.
Discussion – The environments of use are similar to the predicate – Chad Therapeutics Bonsai Model 800 – K070740.

Patient Population –
The patient population of the subject device and predicate is identical.
Discussion – The patient population is equivalent to the predicate device – Chad Therapeutics Bonsai Model 800 – K070740.

Non-Clinical Testing Summary –
Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

Biocompatibility
- ISO 18562-2 – Emissions of Particulate Matter
- ISO 18562-3 – Emissions of VOCs with Toxicological Risk Assessment

Bench testing
- Accelerated Aging
- Flow Comparison
- Flow Regulation Test
- Conservation Testing
- Promoted Ignition Burst Pressure Test
- Environmental Testing
- Altitude Test
- Flow Response Test
- Impact Test

Bench testing –
Performance testing demonstrated that the subject device performs similarly to the predicate device.
Discussion – The test results are similar to the predicate and within pre-defined acceptance criteria.

Biocompatibility –
Discussion – The subject device was found to meet the applicable requirements for biocompatibility safety for the intended population.

Discussion of Differences
The subject device indications for use are similar to the predicate. We have removed the “modified” and “unmodified” language from the predicate device Indications for Use. Also, we have reorganized the language to detail that the device also delivers a constant flow of oxygen, which is the same as the predicate but was not specified in its indications for use statement. We have also removed "i.e., for prescription use only."

The functional differences between the units include body styles and the length of oxygen bolus delivery during inhalation. Since pulse is a fixed time and the breath rate is variable, the percent of the breath that the pulse uses is a function of the breath rate.
- At 15 BPM, the total breath is 4 seconds. With an assumed 1:1 I:E ratio, the inhale time is 2 seconds
- At 20 BPM, the total breath is 3 seconds. With an assumed 1:1 I:E ratio, the inhale time is 1.5 seconds

- At 30 BPM, the total breath is 2 seconds and the same assumed 1:1 I:E ratio, the inhale time decreases to 1 second.
- Using the above examples, the differential between the delivery and length of the bolus fluctuates between .4 second difference at 15 BPM, to less than .2 seconds at 30 BPM.

Discussion – The differences do not raise different questions of safety and effectiveness.

Substantial Equivalence Conclusion

Through testing, the subject device has demonstrated it is substantially equivalent to the predicate device – Chad Therapeutics Bonsai Model 800 – K070740.

Comparative Characteristics	Subject Device Respond OC	Predicate Device Bonsai Model 800 K070740	Similarities / Differences
Manufacturer	Responsive Respiratory, Inc.	Chad Therapeutics	
Prescription Device	Yes	Yes	Similar
Device classification and Product Code	NFB 868.5905	NFB 868.5905	Similar
Indications for Use	The Respond OC Conserving Regulator is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use. It may also be used to deliver a constant flow of oxygen to the patient.	The Chad Therapeutics Bonsai (modified Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511) is intended for use in the same manner as the unmodified device, i.e., for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.	Similar The subject device indications for use are similar to the predicate. We have removed the “modified” and “unmodified” language from the predicate device Indications for Use. Also, we have reorganized the language to detail that the device also delivers a constant flow of oxygen, which is the same as the predicate but was not specified in its indications for use statement. We have also removed "i.e., for prescription use only."
Contraindications	None	None	Similar
Patient Population	Patients that require supplemental oxygen in their home and for ambulatory use	Patients that require supplemental oxygen in their home and for ambulatory use	Similar
Environment of Use	Home and ambulatory use	Home and ambulatory use	Similar
Oxygen Supply	Compressed oxygen cylinder 300 to 3,000 psig	Compressed oxygen cylinder 500 to 3,000 psig	Similar
Cylinder Configuration	CGA 870 Valve	CGA 870 Valve	Similar
Technology	Delivers a pulsed dose of oxygen to patient by sensing inhalation utilizing a standard nasal cannula of 7ft or less in length.	Delivers a pulsed dose of oxygen to patient by sensing inhalation utilizing a standard nasal cannula of 7ft or less in length.	Similar
Pneumatic Design – Non Electric	Yes	Yes	Similar
Features			
Cannula Length	Uses standard single lumen cannula up to 7ft in length	Uses standard single lumen cannula up to 7ft in length	Similar Note: nasal cannula is user supplied

Comparative Characteristics	Subject Device Respond OC	Predicate Device Bonsai Model 800 K070740	Similarities / Differences
Design	2-in-1 design allows patients to switch from conservation mode to standard continuous regulator mode.	Delivers a uniform oxygen pulse at increments. Can be switched to continuous mode.	Similar
Trigger Method	Inspiratory Effort, Negative Pressure	Inspiratory Effort, Negative Pressure	Similar
Conserve Mode	Senses a breath and delivers in first 1/3 of breath cycle	Senses a breath/delivers oxygen in the first half of the inspiratory cycle	Similar Both devices deliver oxygen within a similar time period in the early stages of the inhalation cycle
Selectable Outlet Flow	Continuous – 2, 3, 4 lpm	Continuous – 2 and 4 lpm	Similar
	Conserve – 1-5 lpm	Conserve – 1-6 lpm	Similar
Oxygen Bolus Size (ml) At 20 BPM	Conserve 1 lpm: 11 ml Conserve 2 lpm: 24 ml Conserve 3 lpm: 37 ml Conserve 4 lpm: 46 ml Conserve 5 lpm: 54 ml	Conserve 1 lpm: 11 ml Conserve 2 lpm: 29 ml Conserve 3 lpm: 41 ml Conserve 4 lpm: 50 ml Conserve 5 lpm: 56 ml Conserve 6 lpm: 58 ML	Similar
Outlet Configuration	Cannula Hose Barb	Cannula Hose Barb	Similar
Regulator Outlet Pressure	22 PSI	25 PSI	Similar
Breaths Per Minute (bpm)	Up to 35	14 to 40	Similar
Savings Ration	6:1	6:1	Similar
Ignition Sensitivity and Fault Tolerance	Passed ASTM G 175-24	Passed ASTM G 175-03	Similar