May 4, 2023

US Hyperbaric Network
Jorge Millan
Regulatory Consultant
7600 NW 69th Ave
Medley, Florida 33166

Re: K220290
Trade/Device Name: Revitalair 430+
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: Class II
Product Code: CBF
Dated: March 31, 2023
Received: April 3, 2023

Dear Jorge Millan:

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.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia 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)*
K220290

Device Name
REVITALAIR 430F+

Indications for Use *(Describe)*
The intended use of the Portable Hyperbaric Chamber Revitalair® 430+ is to treat acute mountain sickness under the prescription of a health professional. The medical device is designed for use at health institutions and physician offices.

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 Revitalair 430+

1. Submitter Information

Submitter	US Hyperbaric Network LLC 789 Shotgun Road Weston, FL 33326 USA
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Telephone number	(786) 416-5587
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E-mail	sigmabiomedical@gmail.com
Date prepared:	MAY 3, 2023

2. Subject Device Name

Trade/Proprietary Name:	Revitalair® 430+
Common or Usual Name:	Portable Hyperbaric Chamber
Regulation Number:	21 CFR 868.5470
Regulation Name:	Hyperbaric chamber
Product Code:	CBF
Class	II
Panel	Anesthesiology Devices

3. Predicate Devices

Predicate Devices:	Primary Predicate: Revitalair 430F, K171899 Reference devices: Tampa Hyperbaric Monoplace Chamber, K981938 K051759, Flexi-Lite Hyperbaric Chamber by Pressure Tech

4. Indications for Use:

The intended use of the Portable Hyperbaric Chamber Revitalair® 430+ is to treat acute mountain sickness under the prescription of a health professional. The medical device is designed for use at physician offices and health institutions.

5. Device Description:

The Portable Hyperbaric Chamber Revitalair® 430+ is a hyperbaric semi rigid chamber for low pressures (operating at pressures of no greater than 1.5 atmospheres absolute (ATA)). The operational design pressure of a hyperbaric chamber that encloses a human within its pressure boundary falls within the scope of the American Society of Mechanical Engineers Pressure Vessels Human Occupancy 1 (ASME PVHO 1-2012).

Revitalair® 430+ consists of 2 parts, the cabin or chamber and the compression system or compressor's cabinet. The chamber, weighing 62 pounds, is constructed of an airtight polyester-based plastic fabric joined by aluminum rings, forming a cylinder 900 mm in diameter and 1850 mm in length (Figure 1).

The chamber is inflated with atmospheric air through an electric compressor. Fittings allow the chamber to be connected to compressed air by means of manually controlled valves. The safety or relief valves are operated at pressures of 1.5 ATM which ensures safe operations. The compressor has an additional safety valve for any obstruction of the supply hose from the compressor to the chamber. The Revitalair® 430+ has 10 transparent windows to let in light, 360º viewing and enable easy verification of the patient's comfort from the outside. The Revitalair® 430+ can be operated from the interior as well as from the exterior. After folding it up, the Revitalair® 430+ is placed in its transportation box or in the optional carrying case.

6. Substantially Equivalence Discussion

The following table compares the Portable Hyperbaric Chamber Revitalair® 430+ (abbreviated as Revitalair® 430+) to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	Oxavita S.R.L.	Tampa Hyperbaric Enterprise	Pressure Tech	US Hyperbaric Network	Significant Difference
Trade Name	**Revitalair® 430F**	**Tampa Hyperbaric Monoplace Chamber**	**Flexi-Lite Hyperbaric Chamber**	**Revitalair® 430+**	
510(k)	K171899	K981938	K051759	TBD	
Product Code	CBF	CBF	CBF	CBF	Same
Regulation Number	868.547	868.547	21 CFR868.5470	868.547	Same
Regulation Name	Hyperbaric Chamber	Hyperbaric Chamber	Hyperbaric Chamber	Hyperbaric Chamber	Same

Indications for Use	The intended use of the Portable Hyperbaric Chamber Revitalair® 430F is to treat mountain sickness under the prescription of a health professional. The medical device is designed for use at physician offices and health institutions.	-Carbon monoxide poisoning with or without cyanide complications -Smoke inhalation -Exceptional blood loss or anemia -Clostridial myonecrosis (gangrene) Selected problem chronic wounds -Crush injury, compartment syndrome and acute traumatic ischemia -Compromised skin grafts -Osteomyelitis -Thermal burns -Osteoradionecrosis (radiation burns) Necrotizing soft tissue infections -Air and gas embolisms	The Flexi-Lite Hyperbaric chamber is a rugged & portable hyperbaric chamber intended to be used in treating mild symptoms consistent with Acute Mountain Sickness (AMS) as prescribed by or under the direction of a physician. Caution: Federal law restricts this device td sale by or on the order of a physician.	The intended use of the Portable Hyperbaric Chamber Revitalair® 430+ is to treat acute mountain sickness under the prescription of a health professional. The medical device is designed for use at physician offices and health institutions.	Similar
Max Working Pressure	1.3 ATA -1.4 ATA	3.0 ATA	1.3 ATA	1.3-1.5 ATA	Difference
Prescription - Rx Only	Yes	Yes	Yes	Yes	Same

Target Population	People with medical conditions by altitude sickness	--	Persons with high altitude mountain sickness	People with medical conditions by altitude sickness	Same
Places of Use	Hospitals and clinics	--	Home, Physician Office, Outdoor, Hospital, Sub-acute facility, EMS	Hospitals and clinics	Similar

Device	Revitalair 430F	Revitalair 430+	Difference/ Similarity
510(K)	**K171899**	**K220290**	
Type of construction	Semi rigid	Semi rigid	Same
Dimensions	36.2in x 74.8in	36.2in x 74.8in	Same
Windows	10	10	Same
Transport Belts	2	2	Same
Relief Valves	Yes, Metal	Yes, Metal	Same
Drain Valves	Yes, 2 units only for emptying	Yes, 2 units only for emptying	Same
Operating Pressure	1.3 -1.4 ATA	1.3 ATA-1.5 ATA	Different
Inflation Method	Oil-less compressor	Oil-less compressor	Same
Locking System	System of metal rings	System of metal rings	Same
Materials	Polyester hatched 1100 18x18 Vinyl with phthalate free	Polyester hatched 1100 18x18 Vinyl with phthalate free	Same
Relief Valves	2 by Plastic & Metal	2 by Plastic & Metal	Same
Compressor	Oil-less	Oil-less	Same
Air Filter in the Compressor	Yes	Yes	Same
Pressure Measurement	Yes	Yes	Same
Air Filter Chamber	Yes	Yes	Same
Skills of the Person to Leave the Chamber	Yes	Yes	Same
Operating Temperature	59 °F / 113 °F	59 °F / 113 °F	Similar, range
Contraindications	Patients with: -Pneumothorax, Pulmonary hyper expansion -Eardrum perforation -Asthma -Congenital spherocytosis -The use of any of these drugs: Cisplatinum, Disulfiram(Antabuse) Doxorubicin,Adriami cina, Bleomycina, Sulfamylon, Anphetamines,Nicorette-Nicoderm, Narcotic analgesics, Steroids -Emphysema with CO2 retention. -Fever (>38.5° C), Colds, flu symptoms -Record of medium ear problems or surgery -Convulsions -Optic Neuritis, Optic barotraumas -Pregnancy	Patients with: -Pneumothorax, Pulmonary hyper expansion -Eardrum perforation -Asthma -Congenital spherocytosis -The use of any of these drugs: Cisplatinum, Disulfiram(Antabuse) Doxorubicin,Adriami cina, Bleomycina, Sulfamylon, Anphetamines,Nicorette-Nicoderm, Narcotic analgesics, Steroids -Emphysema with CO2 retention. -Fever (>38.5° C), Colds, flu symptoms -Record of medium ear problems or surgery -Convulsions	Same

	-Airways diseases, Blocked ear canals, Blocked Sinuses -Viral infections -Excessive CO2 Exposure -Decompression sickness	-Optic Neuritis, Optic barotraumas -Pregnancy -Airways diseases, Blocked ear canals, Blocked Sinuses -Viral infections -Excessive CO2 Exposure -Decompression sickness	

Discussion of Similarities:

All systems presented make use of a compressor to provide inflation of a rigid or semi rigid chamber. All systems use similar design principles, designs and technologies to achieve the intended use. All system use drain valves, locking system and materials. The design, technology, materials, manufacturing processes are similar.

Discussion of Differences

When comparing the Revitalair 430+ to the Primary Predicate (Revitalair 430F) there is a difference in the operating pressure. Revitalair 430+ can be operated at maximum of 1.5 ATA, while Revitalair 430F operates at 1.3-1.4 ATA. The operating temperature difference is about 7%-15% higher than the maximum pressure of the 430F. The increase in operating pressure does not raise new safety issues as hyperbaric chambers can be run at higher pressures than 1.3 ATA. The reference predicate K981938, for example, operates at pressures of up to 3 ATA. The 430+ hyperbaric chamber has been validated when operated at 1.5 ATA with safety testing and found to meet safety requirements.

7. Non-Clinical Performance Data:

As part of demonstrating safety and effectiveness of the Revitalair® 430+ Hyperbaric Chamber and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, US Hyperbaric Network completed an number of non-clinical performance tests. Testing was performed as determined by the hazard analysis.

The Revitalair® 430+ Hyperbaric Chamber meets all the requirements for overall design, biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device. The Revitalair® 430+ Hyperbaric Chamber passed all the testing in accordance with internal requirements, and the standards shown below to support substantial equivalence of the subject device:

- Electrical safety testing per IEC 60601-1
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2
- Biocompatibility testing – Cytotoxicity, Sensitization, Irritation, Gas emission VOC, Particulates, Inorganic gases (Ozone, CO, CO2) per ISO 10993 and ISO 18562

In addition to the guidance and standards testing, the following life testing was performed:

- Device Life Report which address's the device's useful life based on reliability analysis of the individual components

- Pressure Testing based on ASME PVHO-1-2007, sections: 2-7.2 al 2-7.7; 4-8.1.1; 4-8.1.2; 4-8.1.4 which address's the device's response to excessive pressures.

8. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

9. Conclusion:

The Portable Hyperbaric Chamber Revitalair® 430+, as designed and manufactured, is determined to be substantially equivalent to the cited primary predicate device Revitalair 430F. Revitalair 430+ and its primary predicate device have the similar intended use, have similar technological characteristics, and are made of similar materials. All devices encompass the same range of physical dimensions and similar ranges of operating pressures.