November 22, 2019

Oxavita S.R.L.
℅ Diane Sudduth
Sr. RA/QA Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K171899
Trade/Device Name: Revitalair 430F
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: Class II
Product Code: CBF
Dated: April 10, 2019
Received: April 11, 2019

Dear Diane Sudduth:

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 D. Courtney
-S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171899

Device Name
Revitalair® 430F

Indications for Use *(Describe)*
The intended use of the Portable Hyperbaric Chamber Revitalair® 430F 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Revitalair® 430F

K171899

1. Submission Sponsor

Oxavita S.R.L.

Tamborini 5813

Buenos Aires, Argentina

Contact: Eduardo Northing

Title: Exports and Logistics

2. Submission Correspondent

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Contact: Dr. Diane Sudduth

Title: Senior Consultant, RA

3. Date Prepared

11/22/19

4. Device Identification

Trade/Proprietary Name:	Revitalair® 430F
Common/Usual Name:	Portable Hyperbaric Chamber
Classification Name:	Chamber, Hyperbaric
Regulation Number:	21 CFR 868.5470
Product Code:	CBF

Device Class: Class II

Classification Panel: Anesthesiology Devices

5. Legally Marketed Predicate Device(s)

K072757, The Dive HD250 and The Grand Dive HD400, SUMMIT TO SEA

6. Indication for Use Statement

The intended use of the Portable Hyperbaric Chamber Revitalair® 430F 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.

7. Device Description

The Portable Hyperbaric Chamber Revitalair® 430F is a hyperbaric chamber for low pressures (operating at pressures of no greater than 1.4 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® 430F 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 above 1.3 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® 430F has 10 transparent windows to let in light, 360º viewing and enable easy verification of the patient's comfort from the outside.

The Revitalair® 430F can be operated from the interior as well as from the exterior.

After folding it up, the Revitalair® 430F is placed in its transportation box or in the optional carrying case.

8. Substantial Equivalence Discussion

The following table compares the Portable Hyperbaric Chamber Revitalair® 430F (abbreviated as Revitalair® 430F) to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

Table 5A – Comparison of Characteristics

Manufacturer	**SUMMIT TO SEA**	**SUMMIT TO SEA**	**Oxavita S.R.L.**	**Significant Difference**
Trade Name	**The Grand Dive HD400**	**The Dive HD250**	**Revitalair® 430F**	
510(k)	K072757	K072757	-	
Product Code	CBF	CBF	CBF	Same
Regulation Number	868.5470	868.5470	868.5470	Same
Regulation Name	Hyperbaric Chamber	Hyperbaric Chamber	Hyperbaric Chamber	Same
Intended Use	Acute Mountain Sickness AMS and its associated mild symptoms	Acute Mountain Sickness AMS and its associated mild symptoms	Acute Mountain Sickness AMS and its associated mild symptoms	Same
Prescription - Rx Only	Yes	Yes	Yes	Same
Target Population	People with medical conditions by altitude sickness	People with medical conditions by altitude sickness	People with medical conditions by altitude sickness	Same
Places of Use	Homes, gyms, offices, outdoor, hospitals and clinics	Homes, gyms, offices, outdoor, hospitals and clinics	Hospitals and clinics	Similar
Weight	32 lb	15 lb	62 lb	Different
Measures Diameter x Length	39.37in x 106.29in (1000mm x 2700mm)	26.6in x 82.7in (675mm x 2100mm)	35.4in x 74.8in (900mm x 1900mm)	Similar
Windows	4	2	10	Different
Transport Belts	4	4	2	Different
Relief Valves	Yes	Yes	Yes, Metal	Same

Manufacturer	**SUMMIT TO SEA**	**SUMMIT TO SEA**	**Oxavita S.R.L.**	**Significant Difference**
Trade Name	**The Grand Dive HD400**	**The Dive HD250**	**Revitalair® 430F**	
Drain Valves	Yes, integrated emptying and filling	Yes, integrated emptying and filling	Yes, 2 units only for emptying	Same
Operating Pressure	4psi / 1.3 ATA	4psi / 1.3 ATA	4psi / 1.3 ATA	Same
Inflation Method	Gast compressor 0523	Gast compressor 0523	Oil-less compressor	Same
Locking System	Simple air tight closure	Simple air tight closure	System of metal rings	Different
Materials	33-39 oz uretane coated nylon	33-39 oz uretane coated nylon	Polyester hatched 1100 18x18 Vinyl with phthalate free	Similar
Relief Valves	Plastic & Metal	Plastic & Metal	2 by Plastic & Metal	Similar
Compressor	Gast oil-less	Gast oil-less	Oil-less	Similar
Air Filter in the Compressor	Yes	Yes	Yes	Same
Pressure Measurement	Yes	Yes	Yes	Same
Air Filter Chamber	Yes	Yes	Yes	Same
Skills of the Person to Leave the Chamber	Yes	Yes	Yes	Same
Operating Temperature ℃	-50°F to 125°F	-50°F to 125°F	59 °F / 113 °F	Similar

Manufacturer	**SUMMIT TO SEA**	**SUMMIT TO SEA**	**Oxavita S.R.L.**	**Significant Difference**
Trade Name	**The Grand Dive HD400**	**The Dive HD250**	**Revitalair® 430F**	
Contraindications	Patients with: Colds, flu symptoms, - Recent Alcohol consumption, - Blocked ear canals, - Blocked Sinuses, - Otic barotraumas, -Excessive CO2 Exposure, -Pulmonary hyper expansion Decompression sickness	Patients with: Colds, or flu symptoms, - Recent Alcohol consumption - Blocked Ear Canals, - Blocked Sinuses, - Otic barotraumas, - Excessive C02 Exposure, - Pulmonary hyper expansion Decompression sickness	Patients with: Colds, or flu symptoms, - Recent Alcohol consumption - Blocked Ear Canals, - Blocked Sinuses, - Otic barotraumas, - Excessive C02 Exposure, - Pulmonary hyper expansion Decompression Sickness	Same
Labeling	Comparable	Comparable	Comparable	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the Revitalair® 430F Hyperbaric Chamber and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, Oxavita completed an number of non-clinical performance tests. Testing was performed as determined by the hazard analysis. The Revitalair® 430F 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® 430F 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, CO_2) 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.

10. 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.

11. Statement of Substantial Equivalence

The Portable Hyperbaric Chamber Revitalair® 430F, as designed and manufactured, is determined to be substantially equivalent to the cited predicate devices.