K120566

JUL 24 2012

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510(K) SUMMARY

SPONSOR
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NAME OF DEVICE

Trade name: O_2PAK™ Portable Oxygen Generator, Model P26029

Common name: Portable oxygen generator

Classification name : 21CFR 868.5440 Portable Oxygen Generator, Product Code CAW

PREDICATE DEVICES

OxySure® Portable Oxygen Generator, Model 615, manufactured by OxySure Systems, The OxySure® FDA 510(k) control number is K052396. Emergency use

INTENDED USE AND INDICATION FOR USE

The O2PAK Portable Oxygen Generator, Model P26029 is intended to provide oxygen for emergency use.

The O2PAK is currently offered to be used under the direction of trained medical military personnel in support for disaster relief, crisis response, wartime operations, deterrence and contingency operations, humanitarian relief situations or peacetime engagements.

PRODUCT DESCRIPTION

The O_2PAK™ is designed to be compact, lightweight, portable, durable and easy to carry for emergency use. O_2PAK™ Model P26029 is the only O_2PAK™ model currently available. Its principle of operation is the same as standard chemical oxygen generators. Oxygen is administered to the patient through a nasal cannula or an equivalent device.

PRODUCT PERFORMANCE TABLE	
Feature	**Pacific Precision Products O_2PAK™ Portable Oxygen Generator, Model P26029**
Intended uses	The O_2PAK™ is intended to provide oxygen for emergency use, under the supervision of trained personnel. Fits in C-Toms Medical Ruck Sack, or equivalent
Environments of use	Locations where emergency oxygen may be needed.
Patient populations	Adult individuals requiring oxygen in an emergency setting.
Solid state chemical oxygen generation	Yes
Portable	Yes
Flow rate	4 to 8 liters per minute
Flow Accuracy	Minimum 4 liters per minute
Delivery Time	Minimum of 22 minutes
Total Oxygen Capacity	Minimum of 90 liters
Medically pure [USP] oxygen	USP 99% Oxygen
Oxygen Outlet Temperature	Maximum 6°C above ambient (at patient)
Oxygen Outlet Pressure	30 psig maximum during initial surge 3 psig maximum during operation
Single use, disposable	Yes
Self-contained	Yes (Cannula NOT included)
Generator storage life	48 months
Weight	< 3 lbs.
Physical dimensions	Length: 9.8 inches Diameter: 4.0 inches
Storage	Optimal :+50°F to +95°F (+10°C to +35°C) Full: -40°F to 158°F (-40°C to +70°C)
Operating temperature range	Optimal: +35°F to +95°F (+2°C to 35°C) Full: -4°F to 155°F (-20°C to 68°C)
Humidity:	Up to 95% Non-Condensing
Surface temperature during operation	< 86° C
Relief Device	Yes ~ 30 psig activation
Flow indicator	Yes
Expended generator indicator	No
Patient interface	Salter Labs P/N 1600 Nasal Cannula or equivalent
Accessories	Salter Labs P/N 1600 Nasal Cannula or equivalent
Contraindications	None
Major components	Chemical oxygen generator with housing (generator bag)

The O_2PAK™ has been qualified to the following environment :

TEST QUALIFICATION TABLE			
DESCRIPTION	**STANDARD**	**COMMENTS**	**RESULT**
Shock	MIL-STD-810G METHOD 516.6	Test per procedure IV— Transit Drop 26x drops on 2x test articles; 13x each	Pass
Vibration (sinusoidal)	IEC 60068-2-6	Frequency Range: 10 to 500 Hz Acceleration Amplitude: 1 g (9.8 m/s^2) Type and Duration of Endurance: 10 sweep cycles in each axis	Pass
Vibration (Random)	IEC 60068-2-64 (IEC 60068-2-34 superseded)	Acceleration Spectral Density: 0.02 g^2/Hz Degree of Reproducibility: low Duration of Conditioning: 9 minutes	Pass
O2 Outlet Temperature	ASTM F1464-93	Test; measured on all test articles.	Pass
O2 Purity	ASTM F1464-93 Section 50.4	Test	Pass
O2 Flow	ASTM F1464-93 Section 50	Test	Pass
Outlet Pressure	ASTM F1464-93 Section 50.7 & 50.8	Test	Pass
High Temperature	MIL-STD-810G METHOD 501.5	Test, recommended and limit high temperature for actuation and performance.	Pass
Low Temperature	MIL-STD-810G METHOD 502.5	Test, recommended and limit low temperature for actuation and performance.	Pass
Humidity	RTCA / DO-160G SECTION 6 CATEGORY A	Test	Pass

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Pacific Precision Products (PPP) is claiming substantial equivalence to the OxySure® Portable Oxygen Generator, Model 615 device manufactured by OxySure Systems, Inc. The 510(k) number is K052396 and is currently legally marketed in the United States. The OxySure® portable oxygen generator is intended to produce oxygen for emergency use.

Feature	Predicate Device OxySure™ Portable Oxygen Generator, Model 615 (K052396)	Proposed Device Pacific Precision Products O_2PAK™ Portable Oxygen Generator Model P26029
Flow rate	Approximately 6.5 liters per minute	Approximately 4 to 8 liters per minute
Flow Delivery Accuracy	6 liters per minute for 15 minutes	4 liters per minute for minimum of 22 minutes
Total Oxygen Capacity	Approximately 90 liters	Minimum of 90 liters
Oxygen Percent in Outlet Gas	USP 99%	USP 99%
Delivery Pressure At Gas Outlet	Unknown	Maximum 3 psig (after surge)
Gas temperature at Gas Outlet	Unknown	Maximum 6° C above ambient

CONCLUSION

The intended use of the O_2PAK™ Portable Oxygen Generator, Model P26029 is similar to the legally marketed predicate device mentioned above; both the proposed device and the predicate device are intended to produce oxygen. Note, The O2PAK is currently offered to be used under the direction of trained medical military personnel in support for disaster relief, crisis response, wartime operations, deterrence and contingency operations, humanitarian relief situations or peacetime engagements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 24 2012

Mr. Gerald White
Quality Assurance Manager
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9671 Irvine Center Drive
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Re: K120566
Trade/Device Name: O2PAK
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: July 3, 2012
Received: July 3, 2012

Dear Mr. White:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
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Enclosure

Indications for Use

510(k) Number: K120566
Device Name: O2PAK
Indications for Use: The O2PAK™ Portable Oxygen Generator, Model P26029 is intended to provide oxygen for emergency use; the O2PAK™ is currently offered to be used under the Direction of trained medical military personnel in support for disaster relief, crisis response, wartime operations, deterrence and contingency operations, humanitarian relief situations or peacetime engagements.

Prescription Use _XXX___AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subparts D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

L Schuttes

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schuttes

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120566