K112546

DEC 27 2011

Non-Confidential Summary of Safety and Effectiveness

O-Two Medical Technologies
7575 Kimbel St.
Mississauga, Ontario L5S1C8
Canada
Tel – 905-677-9410

Official Contact: Ammar Al-Dojaily

Application Date: Aug. 24, 2011

Proprietary or Trade Name: o_two CPAP System

Common/Usual Name: CPAP device

Classification Name: Positive End Expiratory Pressure Breathing Apparatus (21 CFR 868.5965, product code: BYE)

Device Class: Class II

Classification Panel: Anesthesiology

Predicate Devices:

CAREvent Handheld CPAP System
- Manufactured by O-Two Medical Technologies Inc.
- 510(k) number K093862

Boussignac CPAP Device
- Manufactured by Vygon S. A.
- 510(k) number K013884

Device Description:

The o_two CPAP device provides a constant positive airway pressure to the lungs of patients in respiratory distress from Pulmonary Emphysema, Congestive Heart Failure and a number of other obstructive airway conditions. This open system has no moving parts and uses a "vectored flow valve" to create a wall of resistance to expiration and an additive flow to inspiration. By varying the oxygen flow through the valve the baseline pressure can be raised or lowered to maintain a positive airway pressure. The rise in baseline pressure keeps alveoli from collapsing, forces fluid in the lungs back intro the interstitium and improves medication delivery.

The device is a restricted medical device intended for use by qualified medical personnel under the direction of a physician.

Indications for Use:
o_two CPAP System is intended to provide a constant positive airway pressure to spontaneously breathing patients in the hospital environment and emergency medical service applications to treat patients in respiratory distress.

Patient Population:
Spontaneous breathing adult and pediatric patients requiring respiratory support.

Contraindications:
- Patients undergoing procedures with flammable anesthetic gases;
- Patients undergoing hyperbaric treatment.

Comparative table:

Characteristic	O_two CPAP System	Boussignac CPAP Device (K013884)	CAREvent Handheld CPAP System (K093862)
Intended Use	o_two CPAP System is intended to provide a constant positive airway pressure to spontaneously breathing patients.	The BoussignacB C. P.A. P. Device is intended to provide CPAP to spontaneously breathing patients.	Provide constant positive airway pressure for spontaneous breathing patients require respiratory support
Environments of use	Hospital, pre-hospital (EMS) environments	Hospital and pre-hospital environment.	Hospital, pre-hospital (EMS) environments
Patient population	Spontaneous breathing adult and pediatric patients	Spontaneous breathing adult and pediatric patients	Spontaneous breathing adult and pediatric patients
Operating principles	An open system with no moving parts and uses a "vectored flow valve" to create a wall of resistance to expiration and an additive flow to inspiration. By varying the oxygen flow through the valve the baseline pressure can be raised or lowered to maintain a positive airway pressure. The rise in baseline pressure keeps alveoli from collapsing, forces fluid in the lungs back intro the interstitium and improves medication delivery.	An open system with no moving parts and uses a "virtual valve" to create a wall of resistance to expiration and an additive flow to inspiration. By varying the oxygen flow through the valve the baseline pressure can be raised or lowered to maintain a positive airway pressure. The rise in baseline pressure keeps alveoli from collapsing, forces fluid in the lungs back intro the interstitium and improves medication delivery.	Pneumatic, demand flow system

Input range	0-25 L/min variable flow source	0-25 L/min variable flow source	45 to 87 PSI
Patient connection	Face Mask.	Face Mask.	Tubing with external expiratory valve, manometer and mask
Displays	Manometer (optional)	Manometer (optional)	Manometer
Safety features	Open system and main body design which limits airway pressure rise above 30 cm H2O in case of un intentional exhaust port blockage.	Open system design but exhaust port could be un intentionally blocked causing a dangerous rise in patient airway pressure.	Internal high pressure release (at 40 cmH_2O), anti-suffocation valve on patient valve port
Patient support modes	CPAP	CPAP	CPAP
Peak Flow on Demand (L/min)	Unlimited (open system).	Unlimited (open system).	120
CPAP levels (cmH_2O)	0 - 20	0-10	0 - 20
Materials in gas pathway	Polycarbonate, PVC and brass	Polycarbonate, PVC	Polycarbonate, PC, Brass, Aluminum & stainless steel
Accessories	N/A	Mask, Manometer and Nebulizer.	Disposable patient circuit with mask, head strap, manometer, oxygen hose

Differences Between Other Legally Marketed Predicate Devices:

The proposed device is viewed as substantially equivalent to the predicate devices, K013884 and K093862, in terms of design, materials of composition, indications for use, performance, and function.

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

Mr. Ammar Al-Dojaily
Engineering Manager
O-Two Medical Technologies
7575 Kimbel Street
Mississauga, Ontario
CANADA L5S 1C8

DEC 2 7 2011

Re: K112546
Trade/Device Name: o_two CPAP System
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive End Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: December 21, 2011
Received: December 21, 2011

Dear Mr. Al-Dojaily:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: o_two CPAP System

Indications for Use:

o_two CPAP System is intended to provide a constant positive airway pressure to spontaneously breathing patients in the hospital environment and emergency medical service applications to treat patients in respiratory distress.

Prescription Use X AND/OR **Over-The-Counter Use** _____
(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K112546