RESPONSIVE RESPIRATORY INC.
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K061785

SEP - 7 2006

Section 3

510(K) Summary and Substantial Equivalence Comparison

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K061785
Trade Name: Cyl-Fil Oxygen System

1. **Submitter's Identification**:

Responsive Respiratory, Inc.
261 Wolfner Drive
Fenton, MO 63026

Tel: 636-600-4030
Fax: 636-600-4035

Date Summary prepared: June 21, 2006
Amendment - August 9, 2006

Contact Person: Mr. Thomas K. Bannon
President

Ext. 2701
Email: tkb@respondo2.com

2. **Name of Device**:

Cyl-Fil Oxygen System

2a. **Class and Product Code**:

Class 1, 21CFR 868.2700 73 CAN

3. **Predicate Device Information**:

Regulators & Conserving Regulators

Inovo Inc. – Oxygen Conserving Regulator #K031983
Same components, material and design as Cyl-Fil regulator.

Victor Equipment (Thermadyne) – K891771 (6-23-1989)

MADA Medical – K950777 (4-14-1995)

Erie Medical - K780359 (4-4-1978)

Precision Medical - K901831 (8-14-1990)

Oxygen Cylinder Valve – Class 1 (unclassified) - Product Code ECX

Cavagna Group –

1. The International Standard ISO 10297 Transportable Gas Cylinders – Cylinder Valves – Specifications & Type Testing.
2. International Standard ISO 15996 Gas Cylinders – Residual Pressure Valves – General Requirements & Type Testing
3. As well as following CGA recommendations.

Sherwood - Follows CGA recommendations, ISO certified

Oxygen Cylinders – Class 1 (unclassified) – Product Code KGA

Luxfer Gas Cylinders – Cylinders are manufactured to DOT-3AL 2216 and TC-3ALM 153 specifications. Follows DOT guidelines for "Compressed gas cylinders". ISO certified

Catalina Cylinders – Cylinders are manufactured to DOT-3AL 2216 and TC-3ALM 153 specifications. Follows DOT guidelines for "Compressed gas cylinders.

4. **Device Description:**

The Responsive Respiratory Cyl-Fil Oxygen System is a two component system. The first component is a high pressure regulator that delivers USP Grade oxygen at two pressure settings. The second component is a lightweight, portable high pressure cylinder with an oxygen specific post valve (similar to CGA-870 with an additional pin/hole location unique to the Cyl-Fil system) that incorporates a residual pressure retention device to insure that the USP oxygen is always retained in the cylinder. The portable cylinder is prepared and filled with USP oxygen according to industry and FDA requirements.

A supply cylinder supplies USP oxygen to the inlet connection (standard CGA-540) of the Cyl-Fil regulator. The Cyl-Fil regulator pressure setting delivers USP oxygen to the Cyl-Fil portable cylinder at a pressure and rate that does not exceed the safety rating of the cylinder, according to the cylinder manufacturer's specifications. The second Cyl-Fil regulator pressure setting delivers USP oxygen to an auxiliary outlet connection (CGA-1240) for continuous oxygen therapy support in the home.

5. **Intended Use**:

The Cyl-Fil Oxygen System is used by patients who have been prescribed oxygen for ambulatory use. Cyl-Fil regulator allows the patient to maintain a supply of oxygen in their home that delivers the prescribed flow per the physician and also allows the patient to use the primary oxygen cylinder to fill the Cyl-Fil portable cylinder for their ambulatory needs.

6. **Comparison to Predicate Devices**:

The Cyl-Fil regulator is substantially equivalent to other Class I Oxygen Regulators and Inovo's Oxygen Conserving Regulator (Class 2). These companies are Victor Equipment Co., MADA Medical, Erie Medical, Precision Medical and Inovo Inc. Our design is of an all brass construction which uses the same components, materials and design as Inovo's Conserving Regulator K031983.

The Cyl-Fil portable cylinder valve is substantially equivalent to other Class I Oxygen cylinder valve manufacturers. These companies are Sherwood Valve Co. a division of Harsco Corp. and Cavagna Group. Both are active members in the Compressed Gas Association (CGA) which sets the standards with compressed gases.

There are three technological characteristic differences between Cyl-Fil and the other predicate devices.

6a. The Cyl-Fil regulator has two outlets preset to deliver specific pressures and may be used in conjunction. The initial outlet connects the Cyl-Fil portable cylinder which has a proprietary connection to maintain system integrity. This regulator limits the maximum pressure and rate of flow.

6b. The second outlet allows for use in the home setting.

The Cyl-Fil is substantially equivalent in safety and effectiveness to the predicate devices referred above "#3 Predicate Device Information".

6c. The Cyl-Fil valve is designed to maintain a residual pressure to eliminate the need to evacuate between refills due to contamination. The residual pressure retention maintains a positive pressure in the cylinder (14 PSI to 72PSI). The valve includes a proprietary pin index connection to fit only the Cyl-Fil regulator which maintains system integrity.

There is no significant difference in safety and effectiveness between Cyl-Fil and the above predicate devices.

7. **Discussion of Non-Clinical Tests Performed for Determining Substantial Equivalence**

We have followed the tests associated with all brass constructed regulators and brass post valves. All of the components are designed for use in 100% pure oxygen applications and tested accordingly. Performance Testing Included:

- Hydrostatic Test
- Proof Pressure Test
- Cycle Test
- ASTM G175 (Cyl-Fil Regulator, K031983)
- ISO 10297 & ISO 15996 (Cyl-Fil Valve)

8. **Conclusions:**

The subject device, the Responsive Respiratory, Inc., Cyl-Fil Oxygen System has the same intended use as the predicate regulators and valves listed. The additional features incorporated allow the patient to utilize the supply gas more effectively. Moreover, the manufacturers of the Cyl-Fil regulator (INOVO Inc.), Cyl-Fil valve (Cavagna Group) and cylinder (Luxfer gas Cylinders) for Responsive Respiratory Inc. are established in the market and have demonstrated their commitment to quality through previous FDA involvement and membership to associations that instill safety to the industry (CGA) and (DOT).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2006

Mr. Thomas K. Bannon
President
Responsive Respiratory, Incorporated
261 Wolfner Drive
Fenton, Missouri 63026

Re: K061785
Trade/Device Name: Cyl-Fil Oxygen System
Regulation Number: 21 CFR 868.2700
Regulation Name: Pressure Regulator
Regulatory Class: I
Product Code: CAN, ECX and KGA
Dated: July 31, 2006
Received: August 1, 2006

Dear Mr. Bannon:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number: K061785

Device Name: Cyl-Fil Oxygen System

Indications for Use:

The Cyl-Fil Oxygen System is intended to provide supplemental oxygen by prescription only. Cyl-Fil is a two component system. The first component consists of a high pressure regulator that delivers USP oxygen from a supply cylinder having two pressure settings. The second component is a light-weight portable, high pressure cylinder that is refilled by use of the Cyl-Fil pressure regulator.

The intended patient population is to supply, by prescription only, supplemental oxygen to patients requiring additional oxygen.

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

(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: K061785