SEQUAL

510(k) Summary K120785

OCT 25 2012

Submitter Information:

Submitter: Chart SeQual Technologies Inc.
12230 World Trade Drive, Suite 100
San Diego, CA 92128

Contact: Brian Jarrell, Manager of Quality and Regulatory
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Date of Summary: September 10, 2012

Device Name:

Proprietary Name: eQuinox Oxygen System
Common Name: Oxygen Concentrator
Classification of Device: Generator, Oxygen, Portable as per 21 CFR 868.5440

Predicate Device Equivalence:

Chart SeQual Technologies is claiming substantial equivalence to the following legally marketed predicate devices:

K013931 – OMNI Oxygen System
K083163 – OMNI 2 Oxygen System

Description of Device:

The eQuinox Oxygen System is an oxygen concentrator that provides continuous flow or in pulse mode, an oxygen bolus. The eQuinox Oxygen System is based on pressure swing adsorption (PSA) principles. The eQuinox Oxygen System operates from AC power, DC power, or rechargeable batteries. This device delivers supplemental oxygen for patients through the molecular sieve beds and is designed to conserve the use of oxygen while operating in pulse flow mode. During pulse flow mode, oxygen is delivered to the patient through a pulse flow valve when the start of inhalation is detected.

The eQuinox Oxygen System consists of pneumatic and electrical components, AC power supply, DC cable and lithium ion batteries. The system has inlet filtration, air compressor, and

Synthetic Zeolite molecular sieve beds with a rotary valves, outlet filtration, electronic flow control and audible / visual alarms.

Intended Use:

The eQuinox Oxygen System is intended for the administration of supplemental oxygen.

The eQuinox Oxygen System is prescription legend required.

Technological Characteristics:

The eQuinox Oxygen System technology employed to generate oxygen is based on pressure swing adsorption (PSA) principles. This is identical to the technology employed within the predicate devices.

Device Comparison Table

	Chart Sequal Technologies Inc. eQuinox Oxygen System 510(k) K120785	Sequal Technologies Inc. OMNI 2 Oxygen System 510(k) K083163	Sequal Technologies Inc. OMNI Oxygen System 510(k) K013931
Concentration (in %) at:			
1.0 LPM Continuous	90 ± 3	93 ± 3	90 ± 3
2.0 LPM Continuous	90 ± 3	93 ± 3	90 ± 3
3.0 LPM Continuous	90 ± 3	93 ± 3	90 ± 3
16mL Pulse Mode	90 ± 3	93 ± 3	90 ± 3
32mL Pulse Mode	90 ± 3	93 ± 3	90 ± 3
48mL Pulse Mode	90 ± 3	93 ± 3	90 ± 3
64mL Pulse Mode	90 ± 3	93 ± 3	90 ± 3
80mL Pulse Mode	90 ± 3	93 ± 3	90 ± 3
96mL Pulse Mode	90 ± 3	93 ± 3	90 ± 3
128 mL Pulse Mode	90 ± 3	-	-
160 mL Pulse Mode	90 ± 3	-	-
192 mL Pulse Mode	90 ± 3	-	-
Weight	12 lbs	10 lbs	17.9 lbs
Width	10.8"	-	12.3 inches
Depth	7.3"	-	7.1 inches
Diameter	-	4.4 inches	-

Height	15.5"	26 inches	19.3 inches
Power Consumption	Continuous Mode • 42 Watts @ 1LPM • 110 Watts @ 3LPM Pulse Mode • 36 Watts @ 16mL • 60 Watts @ 96mL • 110 Watts @ 3 LPM	Continuous Mode • 52 Watts @ 1LPM • 128 Watts @ 3LPM Pulse Mode • 39 Watts @ Setting 1 (16mL) • 76 Watts @ Setting 6 (96mL)	Continuous Mode • 52 Watts @ 1LPM • 145 Watts @ 3LPM Pulse Mode • 44 Watts @ Setting 1 (16mL) • 85 Watts @ Setting 6 (96mL)
Output pressure	5.0 psig nominal	5.0 psig nominal	5.0 psig nominal
Flow Adjustment, Type and Range of Readout	• Continuous Flow: 0.5 – 3 LPM • Pulse Mode: 16mL – 192 mL • Readouts by LCD Display	• Continuous Flow: 1 – 3 LPM • Pulse Mode: 16mL – 96 mL • Readouts by LCD Display	• Continuous Flow: 0.5 – 3 LPM • Pulse Mode: 1 – 6 (Equivalent to 16mL – 96ml) • Readouts by LED Display
Electrical Requirements	• AC (100 VAC, 50/60 Hz) • DC, 12 V Nominal • Power Cartridge 88 W-Hrs	• AC (100 VAC, 50/60 Hz) • DC, 12 – 24 V Nominal • Power Cartridge 88 W-Hrs	• AC (100 VAC, 50/60 Hz) • DC, 12V Nominal • Power Cartridge 195 W-Hrs
Alarms	• Loss of Power • Low Oxygen Concentration • O2 Flow High or Low • No Inspiratory Detect in Pulse Mode • Low Power Cartridge • Unit Malfunction	• Loss of Power • Low Oxygen Concentration • O2 Flow High or Low • No Inspiratory Detect in Pulse Mode • Low Power Cartridge • Unit Malfunction	• Loss of Power • Low Oxygen Concentration • O2 Flow High or Low • No Inspiratory Detect in Pulse Mode • Low Power Cartridge • Unit Malfunction
High Compressor Pressure Relief	Integrated with ATF Module to relieve system pressure > 15 psig	Integrated with ATF Module to relieve system pressure > 15 psig	Integrated with ATF Module to relieve system pressure > 15 psig
Oxygen Concentration Warning	70 – 85 %	70 – 85 %	70 – 85 %
Oxygen Concentration Low	< 70%	< 70%	< 70%
Visual Indicators	• Red LED for high priority alarms • Yellow LED for low / medium priority alarms • Green to indicate system is function properly	• Red LED for high priority alarms • Yellow LED for low / medium priority alarms • Green to indicate system is function properly	• Red LED for high priority alarms • Yellow LED for low / medium priority alarms • Green to indicate system is function properly
Oxygen System Monitor	Ultrasonic	Ultrasonic	Ultrasonic

PSA Valve Type	Rotary	Rotary	Rotary
Compressor	Brushless DC – Piston Type	Brushless DC - Scroll Type	Brushless DC – Piston Type
Filtration	Dust Compressor Inlet HEPA	Dust Compressor Inlet HEPA	Dust Compressor Inlet HEPA
Intended Use	The eQuinox Oxygen System is intended for the administration of supplemental oxygen. The eQuinox Oxygen System is prescription legend required.	The OMNI 2 Oxygen System is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities. The OMNI 2 Oxygen System is prescription legend required.	The Model 1000 OMNI Oxygen System is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities. The OMNI Oxygen System is prescription legend required.

Performance Data:

Performance testing demonstrates that the eQuinox Oxygen System is compliant with ISO 8359 standard for Oxygen Concentrators. Testing also demonstrates that the product electrical safety and electromagnetic compatibility are substantially equivalent to predicate device and are in compliance with IEC 60601-1 and IEC 60601-1-2 standards.

Conclusion:

Based on the design, testing, and intended use, the eQuinox Oxygen System is substantially equivalent to the currently marketed devices.

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

Caire, Incorporated
C/O Chart SeQual Technologies, Incorporated
Mr. Brian Jarrell
Manager, Quality Assurance & Regulatory Affairs
12230 World Trade Drive, Suite 100
San Diego, California 92128

OCT 25 2012

Re: K120785
Trade/Device Name: eQuinox Oxygen System
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: September 10, 2012
Received: September 25, 2012

Dear Mr. Jarrell:

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

Chart SeQual Technologies Inc.
12230 World Trade Drive, Suite 100, San Diego CA 92128 USA

Indications for Use Statement

Applicant: Chart SeQual Technologies Inc.

510(k) Number (if known):

Device Name: eQuinox Oxygen System

Indications For Use:

The eQuinox Oxygen System is intended for the administration of supplemental oxygen.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

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

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