K083163

510(k) Summary

OCT 20 2009

Submitter Information:

Submitter:	SeQual Technologies, Inc. 11436 Sorrento Valley Road San Diego, CA 92121
Contact:	Brian Jarrell, Director of Quality and Regulatory
Phone:	(858) 202-3157
FAX:	(858) 558-1915
Date of Summary:	June 11, 2009

Device Name:

Proprietary Name:	OMNI 2 Oxygen System
Common Name:	Oxygen Concentrator
Classification of Device:	Generator, Oxygen, Portable as per 21 CFR 868.5440
Product Code:	CAW

Predicate Device Equivalence:

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

K013931 - OMNI Oxygen System, Model 1000 (aka: Eclipse Oxygen System)

Description of Device:

The OMNI 2 Oxygen System is an oxygen concentrator that provides up to 3 LPM continuous flow or in pulse mode an oxygen bolus of up to 96 mL (milli-Liter). The OMNI 2 Oxygen System is based on pressure swing adsorption (PSA) principles. The OMNI 2 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 if inhalation is detected.

The OMNI 2 Oxygen System consists of pneumatic and electrical components, AC power supplies, DC cables and lithium ion batteries. The system has inlet filtration, air compressors, and Synthetic Zeolite molecular sieve beds with a rotary valves, outlet filtration, electronic flow control and audible / visual alarms.

Intended Use:

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.

Technological Characteristics:

The OMNI 2 Eclipse Oxygen System operates comparably to the listed predicate device. The PSA technology employed to generate the oxygen is well established, and therefore, raise no new questions of safety and effectiveness.

Performance Data:

The OMNI 2 Oxygen System has a comprehensive test platform that covers system performance, environmental conditions, electromagnetic compatibility (EMC), and software validation. The test platform confirms compliance with ISO 8359 standard for Oxygen Concentrator devices.

Outside agencies provide independent analysis related to compliance with EMC and IEC 60601-1 (Medical Electrical Equipment—Part 1: General Requirements).

The test platform ensures compliance to recognized consensus standards and therefore raises no new questions of safety and effectiveness.

Conclusion:

Based on intended use, technology characteristics, design and performance data the OMNI 2 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 W-O66-0609
Silver Spring, MD 20993-0002

Mr. Brian Jarrell
Director of Quality and Regulatory Affairs
Sequal Technologies, Incorporated
11436 Sorrento Valley Road
San Diego, California 92121-1306

OCT 20 2009

Re: K083163
Trade/Device Name: OMNI 2 Oxygen System
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: June 11, 2009
Received: September 18, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

SeQual Technologies Inc.
11436 Sorrento Valley Road, San Diego CA 92121 USA

Indications for Use Statement

Ver/ 3 – 4/24/96

Applicant: SeQual Technologies Inc.

510(k) Number (if known): K083163

Device Name: OMNI 2 Oxygen System

Indications For Use:

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.

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

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Int510k/induse

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

510(k) Number: K083163