K091541

DEC 31 2009

510(k) Summary

Submitter Information:

Submitter:	SeQual Technologies Co., Ltd 6F-7, No.136, Sec.3, Ren-ai Rd. 10657, Taipei, Taiwan (R.O.C.)
Contact:	Cearo Huang, Director, Engineering & Research Division
Phone:	886-2-2700-2737
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Date of Summary:	January 5, 2009

Device Name:

Proprietary Name:	MESA Oxygen Concentrator, Model 2-6000 Series
Common Name:	Oxygen Concentrator
Classification of Device:	Generator, Oxygen, Portable as per 21 CFR 868.5440

Predicate Device Equivalence:

SeQual Technologies Co., Ltd is claiming substantial equivalence to the following legally marketed predicate devices:
K003472 – Integra Oxygen Concentrators Model 6400-OM
K071397 – DEVILBISS 5 Liter Compact Oxygen Concentrator

Description of Device:

The SeQual Model 2-6000 Series, MESA Oxygen Concentrator, is a 0.5 to 5.0 Liter per minute (LPM) continuous flow pressure swing adsorption (PSA) type system that produces oxygen.

The SeQual Model 2-6000 Series, MESA Oxygen Concentrator, consists of pneumatic and electrical components. The system has inlet filtration, air compressors, heat exchanger, and

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

Intended Use:

The SeQual Model 2-6000 Series, MESA Oxygen Concentrator, is intended for the administration of supplemental oxygen up to 5 LPM. The device is not intended for life support nor does it provide any patient monitoring capabilities.

The device has no contraindications.

Technological Characteristics:

The SeQual Model 2-6000 Series, MESA Oxygen Concentrator, operates comparably to the listed predicate devices. The technology employed to generate the oxygen is well established, and therefore, raise no new questions of safety and effectiveness.

Performance Data:

Results of the oxygen concentration testing to ISO 8359 and ASTM 1464 standards confirm the device meets specifications and is substantially equivalent to the predicate devices.

Conclusion:

Based on the design, performance specifications, tests and intended use, the SeQual Model 2-6000 Series, MESA Oxygen Concentrator 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. Cearo Huang
Director, Engineering & Research
SeQual Technologies Company, Limited
6F-7, No. 136, Sec.3, Ren-ai Rd.
Taipei
CHINA (TAIWAN) 10657

DEC 31 2009

Re: K091541
Trade/Device Name: MESA Oxygen Concentrator, Model 2-6000 Series
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: December 17, 2009
Received: December 23, 2009

Dear Mr. Huang:

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

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

TATUNG SEQUAL

Indications for Use

510(k) Number (if known):

Device Name: MESA Oxygen Concentrator

Indications For Use:

The MESA Oxygen Concentrator (Model No.: 2-6000 Series) is intended to provide supplemental oxygen. It is not intended for life supporting, or life sustaining applications 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 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

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