SEP 1 0 2004

K042262

Special 510(k) Summary

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:	August 11, 2004

Device Name:

Proprietary Name:	Integra Oxygen Concentrator, Model 6323A-OM-10
Common Name:	Oxygen Concentrator
Classification of Device:	Generator, Oxygen, Portable as per 21 CFR 868.5440

Predicate Device Equivalence:

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

K942082 - SeQual Technologies Model 6323-OM Oxygen Concentrator

K003472 - Integra Oxygen Concentrators Model 6400-OM

K013931 - OMNI Oxygen System, Model 1000

Description of Device:

The SeQual Model 6323A-OM-10, Integra Oxygen Concentrator, is a 0.5 to 10.0 Liter per minute (LPM) continuous flow pressure swing adsorption (PSA) type system that produces oxygen.

The SeQual Model 6323A-OM-10, Integra 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 6323A-OM-10, Integra Oxygen Concentrator, is intended for the administration of supplemental oxygen up to 10 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 6323A-OM-10, Integra 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 6323A-OM-10, Integra Oxygen Concentrator is substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2004

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

Re: K042262
Trade/Device Name: SeQual Model 6323A-OM-10, Integra Oxygen Concentrator,
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: August 17, 2004
Received: August 23, 2004

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.

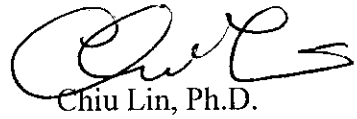
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

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):

Device Name: SeQual Model 6323A-OM-10, Integra Oxygen Concentrator,

Indications For Use:

The SeQual Model 6323A-OM-10, Integra Oxygen Concentrator, is intended for the administration of supplemental oxygen up to 10 LPM. 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)

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

510(k) Number: _____

(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: K042262