APR 2 9 2004

K040892

6.0 510(K) SUMMARY

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
Submitter	Nidek Medical Products, Inc.
Submission Correspondent	Jennifer McWilliams, Quality Assurance Manager Nidek Medical Products 3949 Valley East Industrial Drive Birmingham, AL 35217 Phone (205) 856-7200 ext. 215 Fax (205) 856-0533 jmcwilliams@nidekmedical.com
Date Prepared	April 2, 2004
Proposed Device Trade Name	Mark 5 Nuvo OCSI (M5C5)
Common Name	Oxygen Concentrator or Generator
Classification Name	Generator, Oxygen Portable
Regulation Number	21CFR 868.5440
Class	II
Panel	Anesthesiology
Product Code	CAW
Predicate Device(s)	Mark 5 Nuvo (M5C5) Concentrator K032509 03/18/04
Performance Standards	No applicable mandatory performance standards or special controls have been established for this device under section 514 of the Federal Food, Drug and Cosmetic Act.
Indications for Use	The proposed device is intended solely for medical use in oxygen therapy programs under the supervision of a physician. This device is available by prescription only and is not intended to support or sustain life.

6.0 510(K) SUMMARY CONTINUED

Device Description	The proposed device is an AC powered device that provides a high level of inspired oxygen by separating oxygen from ambient air utilizing pressure swing adsorbers (PSA). Air is drawn into the device with a piston-type compressor and exposed to molecular sieve adsorbent that selectively retains nitrogen and other components until they are released when the pressure is vented to the atmosphere. This cycle is controlled by a motorized rotary 4-way valve and protected from over pressurization by the compressor's pressure relief valve. The device provides a nominal oxygen enriched gas concentration of 90% ±3% at a flow rate of 5 l/min ±10%. The oxygen concentration status indicator (OCSI) board controls the device status indicators including an operator alert when the oxygen concentration in the product gas is below the set point. It is not a life-supporting, life-sustaining or sterile device. The proposed device is a durable, reusable, semi-portable unit weighing approximately 50 pounds [23 kg]. The device is available in both 115V and 230V models that have been designed and validated according to applicable requirements of EN 60601-1-2:2001, IEC 60601-1-2:2001, UL 60601-1:2003, CAN/CSA-C22.2 No 601.1-M90 with A1 & A2:1999, ISO 8359 and FDA Reviewer Guidance document "Excerpts Related to EMI from November 1993" as appropriate to the area of usage. The proposed device may be used with one of the many legally marketed humidifiers, connecting tubing and nasal cannula as prescribed. One of these devices may optionally be included with the device.
Technological Characteristics	The proposed device is exactly the same as the predicate device except the board configuration was modified to incorporate an oxygen concentration status indicator (OCSI).
Nonclinical Performance	The device was tested to applicable requirements EN 60601-1-2:2001, IEC 60601-1-2:2001, UL 60601-1:2003, CAN/CSA-C22.2 No 601.1-M90 with A1 & A2:1999, ISO 8359 and FDA Reviewer Guidance document "Excerpts Related to EMI from November 1993" as appropriate to the area of usage.
Conclusion	The proposed device is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Ms. Jennifer McWilliams
Quality Assurance Manager
Nidek Medical Products, Incorporated
3949 Valley East Industrial Drive
Birmingham, AL 35217

Re: K040892
Trade Name: Mark 5 Nuvo OSCI (M5C5)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: April 2, 2004
Received: April 6, 2004

Dear Ms. McWilliams:

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

5.0 INDICATIONS FOR USE

510(k) Number (if known): K040892

Device Name: Mark 5 Nuvo OCSI (M5C5)

Indications for Use: The Mark 5 Nuvo OCSI (M5C5) Oxygen Concentrator is intended solely for medical use in oxygen therapy programs under the supervision of a physician. This device is available by prescription only and is not intended to support or sustain life.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K040892