K032509

MAR 18 2004

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 C.F.R. § 807.92.
Submitter	Nidek Medical Products, Inc.
Contact Person	Jennifer McWilliams, Quality Assurance Manager 3949 Valley East Industrial Drive Birmingham, AL 35217 Phone (205) 856-7200 ext. 215 Fax (205) 856-0563 jmcwilliams@nidekmedical.com
Date Prepared	August 12, 2003
Name	Mark 5 Nuvo (M5C5)
Classification Names	Oxygen Concentrator
Device Classification	Classification: Generator, Oxygen Portable Classification Panels: Anesthesiology Regulation Number: 21CFR 868.5440
Predicate Device(s)	Mark-5 (M5C5) Concentrator K883591 November 2, 1988 Model 590 Oxygen Concentrator K895141 October 31, 1989
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act
Device Description	The Mark 5 Nuvo (M5C5) oxygen concentrator 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%. It is not a life-supporting, life-sustaining or sterile device.

Device Description Continued

The Mark 5 Nuvo (M5C5) oxygen concentrator 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, and CAN/CSA-C22.2 No 601.1-M90 with A1 & A2:1999 as appropriate to the area of usage. The Mark 5 Nuvo (M5C5) oxygen concentrator is intended to 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.

Indications for Use

The Mark 5 Nuvo (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.

Technological Characteristics

The Mark 5 Nuvo (M5C5) contains features and functions that are similar to the Mark-5 (M5C5) concentrator. The following table briefly describes the proposed changes that do not affect the intended use or alter the fundamental scientific technology of the device.

Component	Predicate Device	Proposed Device
Compressor Cooling	Squirrel Cage Blower	Tubeaxial Fan
Molsiv Adsorbent	MO2	OxySiv
Flow Control	Selectable Fixed-Orifice Valve	Flow Meter (Thorpe Tube)
Outlet Pressure	9 PSI	7 PSI
Circuit Breaker	none	10 Amp
Cabinet Dimensions	Rectangular Design	Contoured Design
Compressor Support	Natural Rubber Isolators	Steel Springs
Labeling	Words	Symbols
Pressure Measurement	Pressure Switches	Pressure Sensor

Nonclinical Performance

The device was tested to applicable requirements EN 60601-1-2:2001, IEC 60601-1-2:2001, UL 60601-1:2003, and CAN/CSA-C22.2 No 601.1-M90 with A1 & A2:1999 as appropriate to the area of usage. Testing was conducted in June 2003 at Intertek Testing Services NA Inc. located at Duluth, GA. and documented in report numbers 3040276-27-1-1and 3040276A.

Conclusion

The Mark 5 Nuvo (M5C5) is substantially equivalent to the legally marketed Mark-5 (M5C5) concentrator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2004

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

Re: K032509
Trade Name: Mark 5 Nuvo (M5C5)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: February 18, 2004
Received: February 20, 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

Item #7

Indications for Use

510(k) Number (if known): K032509

Device Name: Mark 5 Nuvo (M5C5)

Indications for Use: The Mark 5 Nuvo (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: K032509