

K082566

DEC 03 2008

6 510(k) SUMMARY

<b>510(k) Summary</b>	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
<b>Submitter</b>	Nidek Medical Products, Inc. 3949 Valley East Industrial Drive Birmingham, AL 35217 Phone (205) 856-7200 Fax (205)856-0533
<b>Submission Correspondent</b>	Jennifer McWilliams Quality Assurance Manager Nidek Medical Products <a href="mailto:jmcwilliams@nidekmedical.com">jmcwilliams@nidekmedical.com</a> Phone (205) 856-7200 x215 Fax (205)856-0533
<b>Date Prepared</b>	September 2, 2008
<b>Trade Name</b>	
<b>Proposed Device #1</b>	Mark 5 Nuvo Lite OCSI
<b>Proposed Device #2</b>	Mark 5 Nuvo Lite STD
<b>Common Name</b>	Oxygen Concentrator or Generator
<b>Classification Name</b>	Generator, Oxygen Portable
<b>Regulation Number</b>	21CFR 868.5440
<b>Class</b>	II
<b>Panel</b>	Anesthesiology
<b>Product Code</b>	CAW
<b>Predicate Device #1</b>	Nidek's Mark 5 Nuvo OCSI (M5C5) oxygen concentrator cleared under K040892 on April 29, 2004
<b>Predicate Device #2</b>	Nidek's Mark 5 Nuvo (M5C5) oxygen concentrator cleared under K032509 on March 18, 2004
<b>Predicate Device #3</b>	Respironics' Everflo L4 oxygen concentrator cleared under K061261 on June 28, 2006
<b>Performance Standards</b>	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.
<b>Indications for Use</b>	The proposed devices are 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.

**6 510(k) SUMMARY CONTINUED**

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<b>Device Description</b>	<p>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 that are released when the pressure is vented to the atmosphere. This cycle is controlled by an electronic valve and protected from over pressurization by the compressor's pressure relief valve. The device provides a nominal oxygen enriched gas concentration of 90% +6.5%/-3% at a flow rate of 5 l/min ±10%. The proposed device is a durable, reusable, semi-portable unit weighing approximately 32 pounds [14.5 kg]. The device is available in both 115V and 230V models.</p> <p>The device status indicators are controlled by a printed circuit board which is device model specific. For the OCSI model, device status indicators are mains power and oxygen concentration. For the STD model, device status indicators are mains power and system pressure.</p> <p>The proposed device is not life supporting, life sustaining or sterile.</p> <p>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.</p>
<b>Technological Characteristics</b>	<p>The proposed devices are substantially equivalent to the predicate devices. The proposed device status indicators and flow control utilize the same technology as currently used in the Nidek Mark 5 Nuvo concentrators. The proposed device's operating principle is the same as Respironic's L4 Everflo concentrator.</p>
<b>Nonclinical Performance</b>	<p>The device was tested to applicable requirements ISO 8359:1996, EN 60601-1-2:2001, IEC 60601-1:1988 + A1:1991 + A2:1995, UL 60601-1:2003, CAN/CSA-C22.2 No 601.1-M90, and FDA Reviewer Guidance document "Excerpts Related to EMI from November 1993" as appropriate to the area of usage.</p>
<b>Conclusion</b>	<p>The proposed devices are substantially equivalent to the legally marketed predicate devices.</p>

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 0 3 2008

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

Re: K082566  
Trade/Device Name: Mark 5 Nuvo Lite OCSI  
Mark 5 Nuvo Lite STD  
Regulation Number: 21 CFR 868.5440  
Regulation Name: Portable Oxygen Generator  
Regulatory Class: II  
Product Code: CAW  
Dated: September 2, 2008  
Received: September 4, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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 INDICATIONS FOR USE**

510(k) Number (if known): \_\_\_\_\_

Device Names: Mark 5 Nuvo Lite OCSI  
Mark 5 Nuvo Lite STD

Indications for Use: The proposed devices are 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:  K 082566

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