K 123738

FEB 2 8 2013

6 510(k) SUMMARY (REV 12/21/12)

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. 3949 Valley East Industrial Drive Birmingham, AL 35217 Phone (205) 856-7200 Fax (205)856-0533
Submission Correspondent	Van Muth Regulatory Affairs Nidek Medical Products lmuth@nidekmedical.com Phone (205) 856-7200 x242 Fax (205)856-0533
Date Prepared	December 19, 2012
Trade Name **Modified Device #1** **Modified Device #2**	 Mark 5 Nuvo Lite OCSI Mark 5 Nuvo Lite STD
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 #1 **Predicate Device #2**	Mark 5 Nuvo Lite OCSI oxygen concentrator cleared under K082566 on December 3, 2008 Mark 5 Nuvo Lite Std oxygen concentrator cleared under K082566 on December 3, 2008
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 modified 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. There has been no change to the intended use compared to the predicate devices.

6 510(k) SUMMARY (REV 12/21/12) CONTINUED

Device Description

The modified devices are substantially equivalent to the predicate devices. Modifications were made to improve reliability, ease of assembly and serviceability The compressor was changed from a vertically oriented tension spring supported configuration to a horizontally oriented compression spring supported configuration to minimize damage from shipment and handling. The cabinet back was changed from a single part to two parts to simplify assembly and serviceability. Labeling was changed to increase type size for improved readability and to correct some clerical errors. The motor run capacitor was changed to a type that includes an internal protective device. The device circuit breaker was changed from a 10 A rating to a 5 A rating. The modified devices continue to be AC powered devices that provide a high level of inspired oxygen, using the same method as that of the predicate devices, by separating oxygen from ambient air with the pressure swing adsorption (PSA) process. 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 modified 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.

The device status indicators are the same as in the predicate devices. They 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.

The modified device is not life supporting, life sustaining or sterile.

The modified devices may be used with one of the many legally marketed humidifiers, connecting tubing and nasal cannula as prescribed. Recommended accessory devices are described in the User's Guide. One of these devices may optionally be included with the device.

Technological Characteristics	The modified devices are substantially equivalent to the predicate devices as they utilize the same technology currently used in the predicate Nuvo Lite concentrators. The following table indicates the similarities and differences between the modified devices and the predicates:	
Characteristic	**Modified Devices #1 & #2 Mark 5 Nuvo Lite**	**Predicate Devices #1 &#2 Mark 5 Nuvo Lite**
Intended Use	Same as Predicate	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.
Usage Environment	Same as Predicate	Home/Clinical
Operating Life	3 years	5 years
Oxygen Concentration	Same as Predicate	90% (± 6.5/-3%) 0.125 to 5 lpm
Oxygen Concentration Status Indicator	Same as Predicate	OSCI – Yes STD - No
Operating Ranges	Same as Predicate	40°F - 100°F (5°C - 40°C) up to 95% RH
Storage Ranges	Same as Predicate	-4°F - 140°F (-20°C - 60°C) up to 95% RH
Over-Temperature Protection	Same as Predicate	UL 547 Class B 145 +/- 5°C
Avg. Power Consumption	Same as Predicate	330 WATTS
Input Power	Same as Predicate	115V ~ 60 Hz
Flow Regulation Assembly	Same as Predicate	Single-stage diaphragm pressure reducer
Flow Settings	Same as Predicate	0.125 to 5 lpm
Flow Control	Same as Predicate	Flow Valve (12 positionorifice)
Noise Level	Same as Predicate	45 dBA
Compressor	Self-lubricated piston type; Horizontal axis	Self-lubricated piston type Vertical axis
Compressor Free Flow	Same as Predicate	2.7 scfm / 76 l/m
Compressor Support	Compression Steel Springs Horizontal Axis	Tension Steel Springs Vertical Axis
Compressor Relief Valve	Same as Predicate	45 psig/310kPa
Compressor Cooling	Same as Predicate	Tube-Axial Fan

Characteristic	Modified Devices #1 & #2 Mark 5 Nuvo Lite	Predicate Devices #1 &#2 Mark 5 Nuvo Lite
Electric Motor	Same as Predicate	Inductive type
Capacitor	P2 Protection per IEC20252	P0 Class Protection per IEC 20252
Process Timing	Same as Predicate	Timer Printed Circuit Board
Air Separation Module	Same as Predicate	Two beds
Sieve Material	Same as Predicate	Zeochem synthetic zeolite
Outlet Pressure	Same as Predicate	7 psig/48kPa
Filtration	Same as Predicate	Polyurethane foam 10 ppi cells, nominal 5 µm inlet air filter, and 0.3 µm bacterial filter
Protective Enclosure	Same as Predicate	ABS thermoplastic UL-94 V0
Cabinet Dimensions	Same as Predicate	14"W x 9"D x 23"H
Weight	Same as Predicate	32 lbs./14.5kg
Wiring	Same as Predicate	Power cord, power on/off switch, & inter connecting lead wires
Power Cord	Same as Predicate	16 Ga/1.3mm PVC Sheath, Integral
Power Plug	Same as Predicate	Two Blade, Polarized
Circuit Breaker	5 Amp	10 Amp
Tubing Materials	Same as Predicate	PVC, Aluminum, Silicone, & Polyurethane
Labeling	Same as Predicate	English Text & Symbols
Optional Accessories	Same as Predicate	Legally marketed nasal cannula, connecting tubing, & humidifiers
Labeling	Same as Predicate	English Text & Symbols
Nonclinical Performance	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.	
Conclusion	The modified devices include all the same or similar materials, operate with the same technology and demonstrate the same performance so are substantially equivalent to the legally marketed predicate devices.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Mr. Van Muth
Regulatory Affairs
Nidek Medical Products, Incorporated
3949 Valley East Industrial Drive
BIRMINGHAM AL 35217

Re: K123738
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: January 21, 2013
Received: January 31, 2013

Dear Mr. Muth:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): [redacted] K123738

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

Indications for Use: The modified 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)

Lester W. Schultheis Jr
2013.02.28 11:54:06 -05'00'

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

510(k) Number: K123738