May 7, 2020

Nidek Medical Products, Inc.
Olivia Mullen
Compliance/ Regulatory Affairs
3949 Valley East Industrial Drive
Birmingham, Alabama 35217

Re: K192693
Trade/Device Name: Nuvo Nano Portable Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: May 1, 2020
Received: May 1, 2020

Dear Olivia Mullen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192693

Device Name
Nuvo Nano Portable Oxygen Concentrator

Indications for Use *(Describe)*
The Nuvo Nano Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness is made in accordance with the requirements of 21 CFR 807.92.
Submitter	Nidek Medical Products, Inc. 3949 Valley East Industrial Drive Birmingham, AL 35217, USA Phone – 205.856.7200 Fax – 205.856.0533
Contact Person	Olivia Mullen Compliance / Regulatory Affairs omullen@nidekmedical.com Phone – 205.856.7200 ext 220 Fax – 205.856.0533
Date Submitted	07 May 2019
Trade Name	Nuvo Nano Portable Oxygen Concentrator
Common Name	Oxygen Concentrator
Classification Name	Generator, Oxygen, Portable
Regulation Number	21 CFR 868.5440
Prior PMA Submission	No, there has not been a submission for the Nuvo Nano from Nidek Medical Products, Inc.
Equivalent Legally Marketed Device	Respironics SimplyGo Mini Oxygen Concentrator K111885
Description	The Nuvo Nano Portable Oxygen Concentrator (Nano POC) begins its operation with air being pulled into the external air intake filter. This filtered air enters the compressor via a suction resonator and fine filter. Pressurized air then exits the compressor. Next, an electronic valve system directs the air into one of two tubes that contain molecular sieve (sieve beds). The molecular sieve adsorbs (physically attracts) the nitrogen from the air as it is pushed through the sieve beds, this process is called pressure swing adsorption (PSA). As one tube is generating the product gas, the other is being purged of the adsorbed nitrogen. After passing through the oxygen storage tank, the rate of product gas being delivered to the patient is set by a restricting orifice and pulse dose valve based upon detection of a breath. It then passes through a fine particle filter and thru a sensor that detects the oxygen concentration of the product gas before it exits the device through a

510(k) Summary (cont.)

Description (cont.)	fire-resistant outlet. Once the product gas leaves the device, it travels to the patient via oxygen tubing and a cannula inserted in the nose. The Nano POC offers the user multiple options to power the device; a detachable lithium ion battery, replaceable by the patient, and an external AC/DC power supply. The device will charge the lithium ion battery when the battery and power supply are both attached. The device operates from 100V to 240V and at 50/60Hz. The device is approximately 8.3" wide by 3.5" deep by 6.5" high (21.6cm x 8.9cm x 16.5cm). The device weighs about 4.7 pounds (2.1 kg) including the battery. The device provides an intermittent supply of oxygen enriched gas at a concentration between 87% and 96% to patients requiring long-term oxygen therapy without the higher cost of bottled oxygen. The device produces a product pressure of less than 170 kPa (25 psig) and flow is set by a controller that delivers pulsed flow rates nominally equivalent to continuous flow rates of 1 to 5 LPM. The device provides pulsed dose delivery of oxygen to the user through a selection of 5 settings; setting 1 delivering the least and setting 5 delivering the greatest amount of oxygen enriched product gas. Oxygen pulse volume per minute is controlled electronically by monitoring the user's breath rate and therefore adjusting bolus volume to deliver the same amount of oxygen per minute to the user. The device does not contain, nor does it produce, any latex, phthalates, harmful chemicals, animal tissue, blood components, or radioactive materials that the user or patient could physically contact. The user has short term surface contact with the device (PC + ABS cabinet and PET HMI overlay), but the nasal cannula has contact with the face for the duration of the treatment. The product gas also has prolonged contact with the respiratory airways. The device is not invasive nor implanted. The device is not life supporting, life sustaining, sterile, or radioactive. The device does not incorporate a medical substance, animal tissue or blood component. The device is reusable and should be used as often as prescribed, for the duration prescribed. Smoking cigarettes while undergoing treatment, especially during treatment, is a contraindication to the intended purpose of the device. Nidek Medical Products, Inc. warns against the use of oil or grease, using the device around an open flame, and using the device without a prescription from a doctor.
Intended use	The Nano POC is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.

510(k) Summary (cont.)

Predicate Device Comparison

	Predicate Device	**Proposed Device**
Trade Name	Philips Respironics SimplyGo Mini	Nidek Medical Nuvo Nano
Model Number	SimplyGo Mini	855
510(k) submitter	Respironics, Inc.	Nidek Medical Products, Inc.
510(k) number	K111885	K192693
Common Name	Oxygen Concentrator	Oxygen Concentrator
Classification Name	Generator, Oxygen, Portable	Generator, Oxygen, Portable
FDA Product Code	CAW	CAW
Regulation Number	21 CFR 868.5440	21 CFR 868.5440
Intended Use	The Philips Respironics SimplyGo Mini Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.	The Nuvo Nano Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.
Comparison Statement	The proposed device has the same classification information and intended use as the predicate device.	

General		
Power Supply	Lithium Ion Battery AC Power (100 to 240 VAC, 50/60Hz) DC Power (12-16 VDC)	Lithium Ion Battery AC Power (100 to 240 VAC, 50/60Hz)
Battery Options	Standard Battery Extended Battery	Standard Battery
Watt-hour Rating	97.9 Wh (per standard battery)	99 Wh
Battery Duration	Up to 4.5 hours (setting 2 at 20 BPM – standard battery)	Up to 4 hours
Battery Charge Time	4 hours (max recharge for std battery)	Not more than 4 hours
Expected Service Life	5 years – device and accessories	5 years – Nano System 1 year – Molecular Sieve Beds 500 cycles - Battery
Dimensions	9.4 in x 8.3 in x 3.6 in (std battery)	8.3 in x 3.5 in x 6.5 in
Weight	5.0 lbs (std battery)	4.7 lbs
Classification		
	IEC Class II Internally Powered Equipment	IEC Class II Internally Powered Equipment
	Type BF Applied Part	Type BF Applied Part
	IP22	IP22
Comparison Statement	The proposed device has similar general specifications as the predicate device.	

510(k) Summary (cont.)

Predicate Device Comparison

	Predicate Device	**Proposed Device**
Technology		
	Pressure Swing Adsorption (PSA)	Pressure Swing Adsorption (PSA)
User Interface	Capacitive Touch Screen	2.8 inch (7.1 cm) color LCD with membrane switch controls
Comparison Statement	The proposed device has similar technology to the predicate device.	
Performance Specifications		
Average Oxygen Content	At least 87% at all settings (maximum of 96%)	87% to 96% at all settings
Inspiratory Trigger Sensitivity	≤ 0.2 cm H^2O	≤ 0.12 cm H2O
Breathing Frequency	Up to 40 BPM	10 to 40 breaths per minute
Flow Control Settings and Pulse Volumes	Settings 1 2 3 4 5 Breath Rate | Pulse Volumes (mL) 15 11.0 22.0 33.0 44.0 55.0 20 11.0 22.0 33.0 44.0 50.0 25 8.8 17.6 26.4 35.2 40.0 30 7.3 14.7 22.0 29.3 33.3 35 6.3 12.6 18.9 25.1 28.6 40 5.5 11.0 16.5 22.0 25.0 per ISO 80601-2-67	Settings | 1 | 2 | 3 | 4 | 5 Breath Rate | Pulse Volumes (ml) 10 21 42 63 84 100 15 14 28 42 58 66.7 20 10.5 21 31.5 42 50 25 8.4 16.8 25.2 33.6 40 30 7 14 21 28 33.3 35 6 12 18 24 28.6 40 5.3 10.5 15.8 21 25 ±15% at Standard Temperature and Pressure, dry (STDP)* ± 25% over the rated environmental range * STDP is 101.3kPa at an operating temperature of 20°C, dry
Sound Level	43 dBA typical at setting 2 49 dBA typical at setting 5	49 dBA (on setting 2)
Altitude Capability	Up to 10,000 ft	0 to 10,000 ft/3048 m
Storage Temperature	-4 to 140 F/-20 to 60 C	-4 to 158 F/-20 to 70 C
Operating Temperature	41 to 95 F/5 to 35 C	41 to 104 F/5 to 40 C
Relative Humidity	15% to 93%	10% to 90%
Alarms/Alerts		
	No breath / High Breath Rate	No breath detected
	Low Oxygen Concentration	Low O2 concentration (at < 87% and at < 50%)
	Low Battery / Depleted Battery	Low Battery / Battery Depleted / Battery Exhausted
		Battery Too Cold / Too Hot
		System Too Cold / Too Hot
		Low Input Voltage

510(k) Summary (cont.)

Predicate Device Comparison

Alarms/Alerts	Predicate Device	Proposed Device
	Technical Fault Alarm / External Power Failure	Component Fail (sieve bed, power supply, compressor, valve check, cooling fan, breath sensor, oxygen sensor)
	No Flow Alarm	Process Fail (gas supply, system startup, gas delivery, tank pressure)
Comparison Statement	The proposed device has similar performance specifications to the predicate device.	

Standards Compliance	Predicate Device	Proposed Device
EMC	IEC 60601-1-2, 4th edition	IEC 60601-1-2, 4th edition
General Safety	IEC 60601-1 3rd edition	IEC 60601-1 3rd edition
Alarm Systems	IEC 60601-1-8	IEC 60601-1-8
Home Healthcare	IEC 60601-1-11	IEC 60601-1-11
Biological Evaluation	ISO 10993-1	ISO 10993-1 / ISO 10993-10 / ISO 10993-5
Conserving Oxygen	ISO 18779	ISO 18779
Gas Pathways		ISO 18562-1 / ISO 18562-2 / ISO 18562-3
Oxygen Conserving Equip	ISO 80601-2-67	ISO 80601-2-67
Oxygen Concentrators	ISO 80601-2-69	ISO 80601-2-69
Comparison Statement	The proposed device has the same standards compliance as the predicate device.	

Technological Characteristics	The Nano POC is technologically equivalent to the referenced legally marketed device. Both devices share five basic components: 1) a motor driven compressor which is manufactured by the same supplier and has the same operational characteristics, 2) air separation module comprised of an electronically activated control valve and two air separation columns of adsorbent molecular sieve, 3) a flame retardant thermoplastic enclosure, 4) a human-machine interface (HMI) that controls all functions of the device and 5) rechargeable lithium ion batteries and AC/DC power supply as power sources. Both devices have incorporated the same basic design and the same technological characteristics, and utilize the same operating principle.

Technological Characteristics (cont.)	Both of them have been tested to the same electrical and electromagnetic safety standards for medical electrical equipment. Both devices are manufactured under a quality system. The differences between the predicate and subject devices, such as size, storage condition, operating conditions, battery duration, alarm settings, and control panel indicators introduce risks mitigated by the performance testing provided in this submission. Additionally, the Nano POC uses identical materials in the gas pathway as those found in the Kingon P2 (K190304), therefore the methods used to determine biocompatibility are applicable to the Nano POC.

Performance Data

Bench Tests	**Standard**	**Report**	**Results**
Basic Safety and Essential Performance of Oxygen Concentrators	ISO 80601-2-69:2014	R19012	Pass
Basic Safety and Essential Performance of Oxygen-Conserving Equipment	ISO 80601-2-67:2014	R19020	Pass
Basic Safety and Essential Performance of Medical Electrical Equipment	IEC 60601-1:2006 + A1:2013	R19013	Pass
Electromagnetic Disturbances – requirements and tests	IEC 60601-1-2:2015	R19014	Pass
Usability Engineering to Medical Devices	IEC 62366-1:2015 + AC:2016	R19021	Pass
Alarm Systems in Medical Electrical Equipment	IEC 60601-1-8:2007	R19015	Pass
Usability	IEC 60601-1-6:2010	R19020	Pass
Medical Devices used in a Home Healthcare Environment	IEC 60601-1-11:2015	R19016	Pass
Safety Requirements for lithium batteries used in portable applications	IEC 62133-2:2017	EA3373IEC	Pass
Exposure to RFID Readers	AIM 7351731:2017	1909ESU013-U1	Pass
Biocompatibility Tests			
Biological Evaluation of Breathing Gas Pathways	ISO 18562-1:2017	R19011	Pass
Emissions of Particulate Matter	ISO 18562-2:2017	R19011	Pass
Emissions of Volatile Organic Compounds	ISO 18562-3:2017	R19011	Pass
Biological Evaluation of Medical Devices	ISO 10993-1:2009 + AC:2010	R19011	Pass
Cytotoxicity Tests	ISO 10993-5:2009	R19011	Pass
Skin Sensitization / Irritation Tests	ISO 10993-10:2010	R19011	Pass

510(k) Summary (cont.)

Conclusion	Based on information contained in this 510(k) submission, the Nuvo Nano POC has similar intended use, principle of operation, and technological characteristics as the predicate device identified. Performance testing contained in this submission demonstrates the minor differences between devices do not raise different questions of safety or effectiveness. Therefore, in accordance with the 21 CFR 807, Nidek Medical Products, Inc. concludes that the Nuvo Nano Portable Oxygen Concentrator is substantially equivalent to the referenced predicate device.