April 12, 2021

Invacare Corporation
Elijah Wreh
Regulatory Affairs Manager
One Invacare Way
Elyria, Ohio 44035

Re: K203210
Trade/Device Name: Invacare Platinum 5NXG Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: March 10, 2021
Received: March 11, 2021

Dear Elijah Wreh:

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 D. Courtney -S

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)*

Device Name
Invacare® Platinum® 5NXG Oxygen Concentrator

Indications for Use *(Describe)*

The Invacare® Platinum® 5NXG Oxygen Concentrator is indicated for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.

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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510(k) Summary

SUBMITTER per 21 CFR 807.92(a)(1):

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CONTACT PERSON:
Elijah Wreh
Regulatory Affairs Manager

MANUFACTURER:

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Date Prepared per 21 CFR 807.92(a)(1):

March 8, 2021

DEVICE INFORMATION per 21 CFR 807.92(a)(2)

Name of Device:	Invacare® Platinum® 5NXG Oxygen Concentrator
Common or Usual Name:	Portable Oxygen Generator
Classification Name:	Generator, Oxygen, Portable 21 CFR 868.5440
Regulatory Class:	2
Product Code:	CAW
PREDICATE DEVICE:	Invacare® Perfecto$_2$™V Oxygen Concentrator (K200890)
Patient Population:	Patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute

DEVICE DESCRIPTION per 21 CFR 808.92(a)(4)

The subject Invacare® Platinum® 5NXG Oxygen Concentrator device is used by patients who require supplemental oxygen. The device is not intended to sustain or support life. The oxygen concentration level of the output gas ranges from 87% to 96% at an output flow rate range of 1 to 5 liters per minute (LPM). The oxygen is delivered to the user through the use of a nasal cannula.

The concentrator provides supplemental oxygen to patients with respiratory deficiency disorders, in the home, long term care facility or other non-acute patient care facilities. It is not intended to sustain or support life. It is to be used indoors and is intended to support the patient's lifestyle within the home or care facility. The device operates at a nominal 120VAC/60 Hertz supply.

INTENDED USE per 21 CFR 807.92(A)(5)

The Invacare® Platinum® 5NXG Oxygen Concentrator is intended for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.

INDICATIONS FOR USE per FORM FDA 3881

The Invacare® Platinum® 5NXG Oxygen Concentrator is indicated for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.

INDICATIONS FOR USE (IFU) COMPARISON

The Indications for Use statement for the subject device is the same as the previously cleared predicate device.

COMPARISON of TECHNOLOGICAL CHARACTERISTICS with the PREDICATE DEVICE per 21 CFR 807.92(a)(6)

The device comparison shows that the subject device is substantially equivalent in intended use, design, materials, and operational principles to the previously cleared predicate device. The subject and predicate devices use the same technology to extract nitrogen from air. The subject device components met the performance requirements and is substantially equivalent to the predicate device identified throughout this submission and do not raise different questions of safety and effectiveness. The different technological characteristics do not raise different questions of safety and effectiveness as compared to the predicate device.

BASIS of SUBSTANTIAL EQUIVALENCE per 21 CFR 807.100(b)(2)(ii)(A)

The substantial equivalence of the subject device was determined as per the FDA guidance document, "***The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]***" and the technological characteristics which include materials, design, and other device related features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A).

The differences between the new and predicate devices are as a result of updating the pneumatic system, complying to the latest version of ISO 80601-2-69, updating the general structure, and upgrading the operating system, hardware and firmware. The sum of the changes can be assessed using the same consensus standards and acceptance criteria that were used for the predicate device.

The design verification testing and device comparison below demonstrates that the subject device is substantially equivalent to the predicate device. The data generated from the subject device design verification test reports support a finding of substantial equivalence regarding device function and performance and comparison of device specifications and characteristics supports they are substantially equivalent.

Design Characteristics Comparison

Design and Technological Characteristics	Subject Device	Predicate Device
Device Name	Invacare® Platinum® 5NXG Oxygen Concentrator	Invacare® Perfecto$_2$™V Oxygen Concentrator (K200890)
Manufacturer	Invacare Corporation	Same
Intended Use	The Invacare® Platinum® 5NXG oxygen concentrator is intended for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.	Same
Indications for Use	The Invacare® Platinum® 5NXG oxygen concentrator is indicated for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.	Same
Type of Use	Prescription (R_X Only)	Same
Patient Population	Patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute	Same
Oxygen Outlet	Port supplying produced concentrated oxygen	Same
Flowmeter	Adjusts oxygen flow to prescribed setting	Same
Maximum Flow Rate	5.0 L/min	Same
Adjustable Flow Range	1 to 5 L/min in 0.5 L/min increments	Same
Elapsed Time Meter	Displays the cumulative number of hours the unit has operated	Same
Oxygen Purity Fault	If oxygen purity falls below 82% but above 50%	If oxygen purity falls below 85% (±2%) but above 73% (±3%)
Power Indicator	Indicates Device Power Status On/Off	Same
Rated Current Input	3.0 A	3.2 A
Electrical Requirements	120 VAC ± 10%, 60 Hz	Same
Oxygen Output Concentration Levels	87% to 96% at all flow rates	95.6% to 87% at all flow rates
Weight	33 ± 2 lbs.	40 lbs.
Height	24 ± 3/8”	23 ± 3/8”
Width	16 ± 3/8”	15 ± 3/8”
Depth	12 ± 3/8”	Same

DESIGN VERIFICATION TESTING DATA

Design verification testing was performed using the same consensus standards and acceptance criteria that were used for the predicate device to demonstrate a finding of substantial equivalence. The subject device met the performance requirements and is substantially equivalent to the predicate device and do not raise any new questions of safety and effectiveness.

Risk Management

Risk Management has been conducted in accordance with *ISO 14971:2012 - Medical Devices - Application of Risk Management to Medical Devices* for the subject Invacare® Platinum® 5NXG Oxygen Concentrator. The risk-based assessment concluded that the subject device's risk profile remained unchanged and there is no significant impact on the safety or effectiveness of the subject device. The Risk Management File was updated to our current format.

Software Verification Testing

Software Verification Testing, including testing per ISO 80601-2-69 on the finished product, was performed to evaluate the functionality of the of the subject device, including alarms and indicators. Software verification testing was conducted on the subject device as recommended by the FDA's
guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" and IEC 62304:2006 – Medical device software – Software Life Cycle Processes.

Level of Concern: The Level of Concern for the subject device is Moderate.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and Electromagnetic Compatibility (EMC) testing was performed to confirm post-change functionality of the subject device. This includes the following:

- *AAMI ES60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance*
- *IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety & Essential Performance*
- *ISO 80601-2-69 Medical electrical equipment Part 2: Particular Requirements for the Basic Safety and Essential Performance of Oxygen Concentrator Equipment*

- *IEC 60601-1-2: Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*
- *IEC 60601-1-6: Medical Electrical Equipment Part 1-6 General Requirements for Safety - Collateral Standard: Usability*
- *IEC 62366: Medical Devices – Application of Usability Engineering to Medical Devices*
- *IEC 60601-1-11: Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- *IEC 60601-1-8: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

In summary, the sum of the changes can be assessed using the same consensus standards and acceptance criteria that were used for the predicate device and returned substantially the same results as the predicate device demonstrating that the subject device is equivalent in electrical and electromagnetic safety performance to the predicate device.

Biocompatibility Testing

Biocompatibility testing was performed on the subject device components in accordance with FDA guidance document entitled "U*se of International Standard ISO 18562-1, "Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications- Part 1: Evaluation and Testing within a Risk Management Process*." The battery of testing was performed to the following FDA recognized consensus standards:

- *ISO 18562-1:2017, Biocompatibility Evaluation of Breathing Gas Pathways in*
- *Healthcare Applications – Part 1: Evaluation and Testing within a Risk Management*
- *Process*
- *ISO 18562-2:2017, Biocompatibility Evaluation of Breathing Gas Pathways in*
- *Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter*
- *ISO 18562-3:2017, Biocompatibility Evaluation of Breathing Gas Pathways in*
- *Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds*

Testing to detect inorganic gases including Carbon Monoxide (CO) and Carbon Dioxide (CO2), Oxygen (O2) and odour was performed on the subject device. The objective of the test was to assess CO, CO2, O2, and odour and compare their PPM (parts per million) for gas biocompatibility according to the requirements of the "Oxygen 93 %" USP monograph directly to patients.

Performance Testing – Bench

The Invacare® Platinum® 5NXG Oxygen Concentrator is tested to recognized consensus standards for basic safety and essential performance, which can be found in Section "Electromagnetic Compatibility and Electrical Safety." Additional respiratory laboratory testing has been performed on the subject device to demonstrate a finding of substantial equivalence to the predicate device. The battery of testing includes:

- Power and oxygen output performance testing
- ISTA 2A
- Weight
- Sound Testing

ISO 80601-2-69 Medical electrical equipment Part 2: Particular Requirements for the Basic Safety and Essential Performance of Oxygen Concentrator Equipment

In summary, the testing demonstrates that the subject device meets performance specifications and requirements and is substantially equivalent to the predicate device identified throughout this 510(k) submission. The data generated from the performance testing demonstrated that the subject device meets all the performance specifications and requirements and is substantially equivalent to the predicate device.

Animal Study

Animal testing is not required for this submission.

Clinical Testing

Clinical testing is not required for this submission.

CONCLUSIONS per 21 CFR 807.92(b)(3)

The subject device has the same intended use and technological characteristics as the predicate device. The design verification results support a finding of substantial equivalence of the subject device and demonstrate that the subject device will perform as intended in the specified use conditions.