August 6, 2020

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

Re: K200890
Trade/Device Name: Invacare Perfecto$_2$V Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: July 17, 2020
Received: July 20, 2020

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 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)*
K200890

Device Name
Invacare® Perfecto$_2$™V Oxygen Concentrator

Indications for Use *(Describe)*

The Invacare® Perfecto$_2$™V 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:
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Date Prepared per 21 CFR 807.92(a)(1):

August 4, 2020

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

Name of Device: Invacare® Perfecto2™V Oxygen Concentrator

Common or Usual Name: Generator, Oxygen, Portable

Regulation Name: Portable Oxygen Generator

Regulation Number: 21 CFR 868.5440

Regulatory Class: 2

Product Code: CAW

PREDICATE DEVICE: Model Platinum 5 Oxygen Concentrator (K020386)

Patient Population: Patients requiring supplemental oxygen

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

The purpose of this this Premarket Notification [510(k)] submission is to obtain commercial clearance for Invacare® Perfecto2™V Oxygen Concentrator. The subject device is used by patients who require supplemental oxygen. The oxygen concentration level of the output gas

ranges from 87% to 95.6% at an output flow rate range of 1/2 to 5 liters per minute. The oxygen is delivered to the user through the use of a nasal cannula.

INTENDED USE per 21 CFR 807.92(A)(5) for Invacare® Perfecto$_2$™V Oxygen Concentrator

The Invacare® Perfecto$_2$™V 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 for Invacare® Perfecto$_2$™V Oxygen Concentrator

The Invacare® Perfecto$_2$™V 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. The determination was made based on Section 513(i)(1)(E)(i) of the FD&C Act.

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

The device comparison showed that the subject device is substantially equivalent in intended use, design, materials, and operational principles to the previously cleared 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 design verification testing and device comparison 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 comparison, device specifications, and design characteristics.

Design Characteristics Comparison

Design and Technological Characteristics		Subject Device	Predicate Device
Device Name		Invacare® Perfecto$_2$™V Oxygen Concentrator	Invacare Platinum 5 Oxygen Concentrator (K020386)
Manufacturer		Invacare	Invacare
Intended Use		The intended function and use of the Invacare Model Platinum Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.	To provide supplemental oxygen to patients with respiratory disorders by separating nitrogen from room air by way of a molecular sieve. It is not intended to sustain or support life.
Indications for Use		The intended function and use of the Invacare Perfecto$_2$™V Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.	The intended function and use of the Invacare Model Platinum oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.
Oxygen Outlet		Port supplying produced concentrated oxygen	Port supplying produced concentrated oxygen
Flowmeter		Adjusts oxygen flow to prescribed setting	Adjusts oxygen flow to prescribed setting
Flow Rate	**Maximum Flow Rate**	5.0 L/min	5.0 L/min
	Adjustable Flow Range	0.5 – 5 L/min in 0.5 L/min increments	0.5 – 5 L/min in 0.5 L/min increments
Elapsed Time Meter		Displays the cumulative number of hours the unit has operated	Displays the cumulative number of hours the unit has operated
Oxygen Purity, Fault and Power Indicator		Falls below 85% (±2%) but above 73% (±3%)	Falls below 85% (±2%) but above 73% (±3%)
Design Schematic		NEC Microprocessor Control Board	NEC Microprocessor Control Board
Rated Current Input		3.2 A	4.0 A
Electrical Requirements		120 VAC ± 10%, 60 Hz	120 VAC ± 10%, 60Hz
Altitude		Up to 8,000 ft (2438 m) above sea level without degradation of concentration levels. While using a HomeFill System: Up to 6,000 ft (1828 m) above sea level without degradation of concentration levels.	Up to 6000 feet (1828 m) above sea level without degradation of concentration levels. 6,000 ft (1828 m) to 13129 ft. (4000 m) with concentration below 90%.
Oxygen Output Concentration Levels		95.6% to 87% at ½ to 5 L/min	95.6% to 87% at all flowrates
Maximum Output Pressure		5.0 ± 0.5 psi (34.5 ± 3.45 kPa)	5.0 psi, ± 0.5 psi (34.5 ± 3.45 kPa)
Low Flow Alarm		0 L/min. to .5 L/min., Rapid Audible Alarm Beeping	0 L/min. to .5 L/min., Rapid Audible Alarm Beeping
Power Consumption		325W Typical	400W Average
Pressure Relief Mechanism Operation		35 psi ± 5 psi (241 kPa ± 34.5 kPa)	35 psi ± 3.5 (241 kPa ± 24.1 kPa)
Operating Temperature		10 to 35C (50 to 95F) at up to 60% relative humidity	10 to 35C (50 to 95F) at 20-60% relative humidity

DESIGN VERIFICATION TESTING DATA

Design verification testing was performed on the subject device components to demonstrate a finding of substantial equivalence. 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.

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® Perfecto$_2$™V Oxygen Concentrator. The Risk Management Report provides guidance on the principal factors to consider in conducting a risk-based assessment to determine risk associated with the subject device's risk profile. The Risk Management Report involves describing the relationships between a hazard and the ultimate consequences in terms of physical injury or damage. Based on the risk-based assessment performed, the subject device's risk profile remained unchanged and there is no significant impact on the safety or effectiveness of the subject device.

Software Verification Testing

Software Verification Testing was performed to evaluate the functionality of the design, materials, and operational principles of the subject device components. Software verification testing was conducted on the subject device components 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 evaluate the functionality of the design, materials, and operational principles of the subject device components. 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*

In summary, the applicable testing demonstrates that the subject device components are 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 odor was performed on the subject device. The objective of the test was to assess CO, CO2, O2, and odor 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

Performance testing was performed on the subject device to FDA recognized consensus standards for basic safety and essential performance. Additional respiratory laboratory testing has been performed on the subject device to demonstrate a finding of substantial equivalence to the predicate device. The testing includes:

- ISO 80601-2-69 Medical electrical equipment Part 2: Particular Requirements for the Basic Safety and Essential Performance of Oxygen Concentrator Equipment
- Sound Pressure Level Test
- Oxygen Concentration Status Indication Test
- Warm-Up Time Test
- Product Weight Test
- ISTA 2A Test

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was 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 data 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.