5DEPARTMENT 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

September 27, 2016

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

Re: K160630
Trade/Device Name: Invacare® Platinum™ Mobile Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: August 25, 2016
Received: August 26, 2016

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. 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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
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Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160630

Device Name
Invacare® Platinum™ Mobile Oxygen Concentrator

Indications for Use *(Describe)*
The Invacare® Platinum™ Mobile Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders. The device can be used in a home, institution, vehicle, or other environments outside the home.

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.

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510(k) Summary

SUBMITTER: Invacare Corporation
One Invacare Way
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CONTACT PERSON: Elijah N. Wreh
Regulatory Affairs Manager (Pre-Market)
Phone: (440) 329-6840
Email: ewreh@invacare.com

Date Prepared: September 22, 2016

DEVICE
Name of Device: Invacare® Platinum™ Mobile Oxygen Concentrator
Common or Usual Name: Generator, Oxygen, Portable
Classification Name: Portable Oxygen Generator 21 CFR §868.5440

Regulatory Class: II

Product Code: CAW: Generator, Oxygen, Portable

PREDICATE DEVICE: The Invacare Flyer (Model XPO100) (K071928)
No reference devices were used in this submission

Patient Population: Adult Patient Only

Environment of Use: Home, institution, vehicle, or other environments outside the home

DEVICE DESCRIPTION

This Traditional [510(k)] submission is being supplied to the U.S. FDA to obtain authorization to market the Invacare® Platinum™ Mobile Oxygen Concentrator. The Invacare® Platinum™ Mobile Oxygen Concentrator is a portable oxygen concentrator that provides oxygen in pulsed demand flow dosages at settings of P1 through P4. The oxygen concentration level of the output gas ranges from 87% to 95.6%. The device is used with a nasal cannula to direct oxygen from the device to the patient. The Invacare® Platinum™ Mobile Oxygen Concentrator can be used in a home, institution, vehicle, or other environments outside the home. The device is not intended to be life supporting or life sustaining. There is no prior submission for the subject device.

The associated accessories include:

- Invacare® Battery
- Invacare® Battery Charger
- AC Adapter
- DC Power Cable
- Carry Bag

INDICATIONS FOR USE

The Invacare® Platinum™ Mobile Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders. The device can be used in a home, institution, vehicle, or other environments outside the home.

INTENDED USE

The Invacare® Platinum™ Mobile Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders. The Invacare® Platinum™ Mobile Oxygen Concentrator can be used in a home, institution, vehicle, or other environments outside the home. The device is not intended to be life supporting or life sustaining.

INDICATIONS FOR USE COMPARISON

The subject device and the previously cleared predicate device is indicated to provide supplemental oxygen to patients with respiratory disorders. The subject device and the predicate device is intended to be used in a home, institution, vehicle, or other environments outside the home. The subject device is substantially equivalent to the predicate device in regards to intended use to provide supplemental oxygen to patients with respiratory disorders.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The device comparison demonstrates that the subject device is substantially equivalent in design, materials, and operational principles to the previously cleared The Invacare Flyer (Model XPO100) (K071928).

Design Characteristics Comparison

No.	Feature		Subject Device Platinum Mobile Oxygen Concentrator (K160630)	Predicate Device The Invacare Flyer (Model XPO100) (K071928)
1.	**Sieve Bed Material**		Synthetic zeolite OP-76	Synthetic zeolite Z12-07
2.	**Dimensions**	Height	9.45" max	10.0" +/- 1"
		Width	7.5" max	7.0" +/- 1"
		Depth	3.88" max	4.3" +/-1"
		Weight	< 5 lbs. (with standard removable battery)	≤ 7 lbs. (with non-removable internal battery)
3.	**Oxygen Purity Sensor**		Yes	No
4.	**Flow Rates**		Pulse flow P1, P2, P3, P4 Flow volume per minute is 220-880ml	Pulse flow 1, 2, 3, 4, 5 Flow volume per minute is 300-840ml
5.	**Alarms**	Low oxygen purity	Yes	No
		Oxygen sensor failure	Yes	No
		No breath detect	Will supply bolus of O2 if no inhalation detected in 15 seconds. Unit will shut down if no breath is detected for > 120 seconds.	No "Auto-Pulse" feature

PERFORMANCE DATA

Respiratory Testing

Respiratory testing was performed to evaluate the functionality of the design, materials, and operational principles of the subject device. This includes the following:

- *Product Weight Test*
- *Pulse Volume/Pulse Time/Trigger Sensitivity / Oxygen Purity Test*
- *External Battery Charger Charge Time*
- *Oxygen Sensor Accuracy*
- *Oxygen Purity at AC Supply Mains Extremes*
- *Oxygen Purity at DC Power Extremes*
- *Oxygen Purity after Storage Thermal Cycling*
- *Oxygen Purity at Low and High Temperature*
- *Hot – Swapping Batteries*
- *Battery Discharge Times*
- *Battery Charge Times*
- *Oxygen Purity at Low and High Altitude*
- *Software Functional Test*
- *Oxygen Alarms Test*
- *Operational Alarms Test*
- *Full Assembly – Sound Performance Test*
- *POC1 – Battery Charge Time When POC1 Unit Not Running*

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and Electromagnetic Compatibility testing was performed to evaluate the functionality of the design, materials, and operational principles 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 80601-2-67: Medical Electrical Equipment — Part 2-67: Particular Requirements for Basic Safety and Essential Performance of Oxygen Conserving Equipment*
- *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 60601-1-8: Medical electrical equipment – 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*
- *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*

Software Verification Testing

Software Verification Testing was performed to evaluate the functionality of the design, materials, and operational principles of the subject device. This includes the following: 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*."

Level of Concern: The software for this device was considered as a minor level of concern because the subject device is a supplement to a patient's normal oxygen intake. A software failure will not result in injury to a patient or user. The device is not intended to be life supporting or life sustaining.

Biocompatibility Testing

Biocompatibility testing was performed on the subject device raw materials and the test results demonstrated that the subject device is biocompatible. The testing was conducted in accordance with the FDA Blue Book Memorandum #G95 − 1 "Use of International Standard ISO − 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993 − 1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- AAMI / ANSI / ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for *in vitro* Cytotoxicity
- AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Irritation
- ISO 10993-11:2010, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- Volatile Organic Chemicals Using the EPA TO-17 Method
- Particulate Matter (PM)

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

CONCLUSIONS

The subject device has the same intended use and similar technological characteristics as the predicate device. The non-clinical laboratory data support the substantial equivalence of Invacare® Platinum™ Mobile Oxygen Concentrator and demonstrates that the subject device performs as intended in the specified use conditions. Therefore, the subject Invacare® Platinum™ Mobile Oxygen Concentrator is substantially equivalent to the predicate device.