M E M O R A N D U M

TO: FAA Self-Declaration on Portable Oxygen Concentrator (POC)

FROM: Elijah Wreh, Regulatory Affairs Department

DATE: January 21, 2020

SUBJECT: Invacare Corporation Declaration of Portable Oxygen Concentrator to Federal Aviation Administration (FAA) Final Rule

Scope

This Memo to File will serve to document Invacare Corporation self-declaration that the Invacare® Platinum™ Mobile Oxygen Concentrator, Model POC1-100C complies with the U.S. Federal Aviation Administration's Acceptance Criteria for Portable Oxygen Concentrators Used on Board Aircraft; Final Rule as published in the Federal Register, Vol. 81, No. 100 on May 24, 2016, for carriage and personal use onboard aircraft.

Regulatory Requirements

As per the FAA's Final Rule effective as of August 22, 2016, the Invacare Model POC1-100C meets all the FAA's acceptance criteria in §121.574, (e)(1); §125.219, (f)(1); and §135.91, (f)(1) for portable oxygen concentrators:

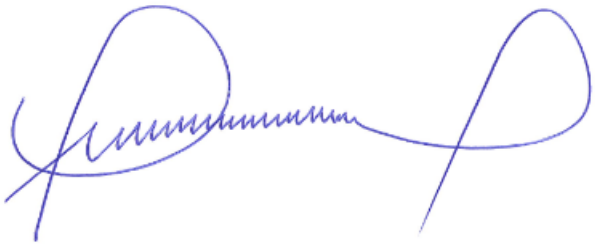
(i) The subject device is legally marketed in the United States in accordance with Section Premarket Notification [510(k)] of the Federal Food, Drug and Cosmetic Act, as amended, and Title 21 CFR Part 807, Subpart E. The subject device was previously cleared under 510(k) number K191159 on August 29, 2019. Please find the attached substantial equivalence letter below for more details.

(ii) Has been tested to and meets the requirements of RTCA DO-160G, Section 21, Category M, for Medical-Personal Electronic Devices that do not radiate radio frequency emissions that interfere with aircraft systems;

(iii) Generates a maximum oxygen pressure of less than 29.0 psig/43.8 psia, (200 kPa gauge) at 68°F (20°C);

(iv) Does not contain any hazardous materials subject to the Hazardous Materials Regulations (49 CFR parts 171 through 180) except as provided in 49 CFR 175.10 for batteries used to power portable electronic devices and that do not require aircraft operator approval;

(v) Has a label on its exterior that will remain affixed for the life of the device containing the following certification statement in red lettering: *"The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft."*



Elijah Wreh
Regulatory Affairs Manager

- Invacare Platinum Mobile Oxygen Concentrator with Connectivity (K191159)

INVACARE CORPORATION
One Invacare Way Elyria, OH 44035 USA
Tel: 440-329-6000 www.invacare.com

August 29, 2019

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

Re: K191159
Trade/Device Name: Invacare Platinum Mobile Oxygen Concentrator with Connectivity
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: July 29, 2019
Received: July 30, 2019

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)*
K191159

Device Name
Invacare® Platinum® Mobile Oxygen Concentrator with Connectivity

Indications for Use *(Describe)*
Invacare® Platinum® Mobile Oxygen Concentrator

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.

Invacare® Mobile Medical Application Accessory Piccolo O2

The Invacare® Mobile Medical Application Accessory PICCOLO O2 is intended for use with the Invacare® Platinum Mobile Oxygen Concentrator POC1-100C device, to allow patients via their Android™ or iOS™ mobile phone or tablet to display device settings, control flow setting, and to collect device performance and usage information for maintenance/ servicing purposes.

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

K191159

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

Invacare Corporation
One Invacare Way
Elyria, OH 44035
Phone: (440) 329-6840
Email: ewreh@invacare.com

CONTACT PERSON:
Elijah Wreh
Regulatory Affairs Manager

MANUFACTURER:
Invacare Corporation
2101 E Lake Mary Blvd
Sanford, FL 32773

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

April 30, 2019

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

Name of Device:	Invacare® Platinum® Mobile Oxygen Concentrator with Connectivity
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:	Invacare® Platinum® Mobile Oxygen Concentrator (K160630)
Patient Population:	Adult Patient Only

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 Mobile Medical Application Accessory Piccolo O_2 which is compatible with the previously cleared Invacare® Platinum® Mobile Oxygen Concentrator, cleared under K160630 on September 27, 2016. Invacare Mobile Medical Application Accessory PICCOLO O2 is a Mobile App is intended to provide useful device performance information to the previously cleared Invacare® Platinum® Mobile Oxygen Concentrator end users such as dosage level setting and fault codes as well as allow the user to control the selected dosage level.

- Invacare® Platinum® Mobile Oxygen Concentrator with Connectivity
- Invacare Mobile Medical Application Accessory for Piccolo O2 use on iOS and Android devices
- POC1 USB Bluetooth Dongle

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

Invacare® Platinum® Mobile Oxygen Concentrator

Invacare® Platinum® Mobile Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders. 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.

Invacare Mobile Medical Application Accessory PICCOLO O2

The Invacare Mobile Medical Application Accessory PICCOLO O2 is intended to allow patients via their Android™ or iOS™ mobile phone or tablet to display device settings, control flow setting, and to collect device performance and usage information for maintenance/servicing purposes.

INDICATIONS FOR USE per FORM FDA 3881

Invacare® Platinum® Mobile Oxygen Concentrator

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.

Invacare Mobile Medical Application Accessory PICCOLO O2

The Invacare Mobile Medical Application Accessory PICCOLO O2 is intended for use with the Invacare Platinum Mobile Oxygen Concentrator POC1-100C device, to allow patients via their Android™ or iOS™ mobile phone or tablet to display device settings, control flow setting, and to collect device performance and usage information for maintenance/servicing purposes.

COMPARISON OF INDICATIONS FOR USE (IFU)

The Indications for Use statement for the subject device is the same as the previously cleared predicate device. The additional indications for use for Piccolo O2 Mobile Medical App are to allow patients via their Android™ or iOS™ mobile phone or tablet to display device settings, control flow setting, and to collect device performance and usage information for maintenance/servicing purposes. 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.
The difference in technology between the previously cleared device and the subject device is the addition of wireless connectivity.

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 subject device components are safe and effective as the predicate device and do not raise different questions of safety and effectiveness. The difference in technological characteristics induced by the software update does not raise new questions of safety and effectiveness. The

design verification testing, device comparison, and dimensional analysis demonstrates that the subject device components are 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, wireless capability and coexistence, dimensional analysis, device specifications, and design characteristics.

Design Characteristics Comparison

Design and Technological Characteristics	Subject Device	Predicate Device
Device Name	Invacare® Platinum® Mobile Oxygen Concentrator with Connectivity	Invacare® Platinum® Mobile Oxygen Concentrator
Manufacturer	Invacare Corporation	Invacare Corporation
510(k) Number	Pending	K160630
Intended Use for Invacare® Platinum® Mobile Oxygen Concentrator	Invacare® Platinum® Mobile Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders. 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.	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 for Invacare® Platinum® Mobile Oxygen Concentrator	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.	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 for Invacare Mobile Medical Application Accessory PICCOLO O2	The Invacare Mobile Medical Application Accessory PICCOLO O2 is intended to allow patients via their Android™ or iOS™ mobile phone or tablet to display device settings, control flow setting, and to collect device performance and usage information for maintenance/servicing purposes.	None
Indications for Use for Invacare Mobile Medical Application Accessory PICCOLO O2	The Invacare Mobile Medical Application Accessory PICCOLO O2 is intended for use with the Invacare Platinum Mobile Oxygen Concentrator POC1-100C device, to allow patients via their Android™ or iOS™ mobile phone or tablet to display device settings, control flow setting, and to collect device performance and usage information for maintenance/servicing purposes.	None
Bluetooth	Bluetooth LE only	None
Operating Environment		
	Home, institution, vehicle, or other environments outside the home	Home, institution, vehicle, or other environments outside the home
Compatible Devices		
	Invacare® Platinum™ Mobile Oxygen Concentrator	Not Applicable
Device Settings changed by software		
App	• Device operating mode • Device usage (Display only) • Change or Control Pulse Flow settings	None

Design and Technological Characteristics		Subject Device	Predicate Device
Sieve Bed Material		Synthetic zeolite	Synthetic zeolite
Dimensions	Height	9.45” max	9.45” max
	Width	7.5” max	7.5” max
	Depth	3.88” max	3.88” max
	Weight	4.9 lbs nominal (with standard removable battery)	< 5 lbs. (with standard removable battery)
Oxygen Purity Sensor		Yes	Yes
Flow Rates		Pulse flow P1, P2, P3, P4, P5 Flow volume per minute is 220-1000ml	Pulse flow P1, P2, P3, P4 Flow volume per minute is 220-880ml
Alarms	Low oxygen purity	Yes	Yes
	Oxygen sensor failure	Yes	Yes
	No breath detects	Supply bolus of O2 if no inhalation detected in 15 seconds. Unit will shut down if no breath is detected for > 120 seconds.	Supply bolus of O2 if no inhalation detected in 15 seconds. Unit will shut down if no breath is detected for > 120 seconds.

DESIGN VERIFICATION TESTING DATA

Design verification testing was performed on the subject device. The device met the performance requirements and is substantially equivalent to the predicate device identified throughout this submission and do not raise any new questions of safety and effectiveness.

Risk Management

Risk Management has been conducted in accordance with *ISO 14971:2007 - Medical Devices - Application of Risk Management to Medical Devices* for the subject Invacare® Platinum® Mobile 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. 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*" 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. 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*

In summary, the applicable testing demonstrates that the subject device is equivalent in electrical and electromagnetic safety performance to the predicate device.

Wireless Coexistence and Cybersecurity

Wireless Coexistence testing has been conducted in line with ANSI C63.27:2017 and IEC 60601-1-2 4th Edition. The function of the product is not impacted if disruption of the dongle wireless communication occurs. Cybersecurity software documentation was created for subject Invacare Mobile Medical Application Accessory PICCOLO O2 device according to FDA guidance document “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” issued on October 18, 2018.

Biocompatibility Testing

Biocompatibility testing was performed on the previously cleared Invacare® Platinum® Mobile Oxygen Concentrator (K160630) in accordance with FDA guidance document entitle "U*se of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*." The battery of testing was performed to the following FDA recognized consensus standards:

- AAMI / ANSI / ISO 10993 - 1:2009/(R) 2013, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
- AAMI / ANSI / ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for in vitro Cytotoxicity
- AMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Irritation
- AAMI / ANSI / ISO 10993-11:2006/(R)2010, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- ISO 14971:2007, Medical Devices - Application of Risk Management to Medical Devices
- 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

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 similar technological characteristics as the predicate device. The difference in technology between the previously cleared device and the subject device is the addition of wireless connectivity.

The design verification data support the safety and performance of the subject device and demonstrate that the subject device will perform as intended in the specified use conditions. The results of the performance testing, software and cybersecurity validation, and risk analysis demonstrate that the subject device is substantially equivalent to the proposed predicate device without raising new questions of safety and effectiveness.