MEMORANDUM

To:	TO WHOM IT MAY CONCERN
From:	Elijah Wreh, Regulatory Affairs Department
Date:	October 4, 2016
Subject:	Invacare Corporation Declaration of Portable Oxygen Concentrator to Federal Aviation Administration (FAA) Final Rule

Invacare Corporation hereby declares that the Invacare® Platinum™ Mobile Oxygen Concentrator, Model POC1-100B, is in compliance 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.

As per the FAA's Final Rule effective as of August 22, 2016, the Invacare Model POC1-100B meets all of 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 was previously cleared under 510(k) number K160630 on September 27, 2016. 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;

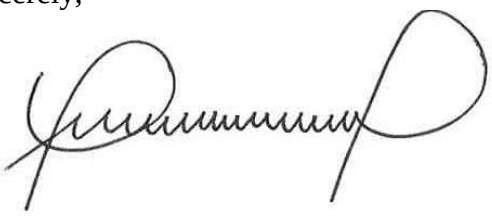
(iii) Generates a maximum oxygen pressure of less than 29.0 psig/43.8 psia, (200 kPa gauge) at 68°F (20°C);

(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."*

If there are any questions, or if further information is needed, please don't hesitate to contact the undersigned below by phone at (440) 329-6840 or by email at ewreh@invacare.com.

Sincerely,



Elijah N. Wreh
Regulatory Affairs Manager (Pre-Market)

- Invacare® Platinum™ Mobile Oxygen Concentrator (K160630)

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure