March 19, 2021

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

Re: K202379
Trade/Device Name: Invacare AVIVA Storm RX Power Chair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 10, 2021
Received: February 16, 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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202379

Device Name
Invacare AVIVA Storm RX Power Wheelchair

Indications for Use *(Describe)*
The Invacare AVIVA Storm RX Power Wheelchair is indicated to provide mobility and positioning to persons limited to a sitting position.

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 Information per 21 CFR 807.92(a)(1)

SPONSOR:	Invacare Corporation One Invacare Way Elyria, OH 44035

PRIMARY CONTACT:	Elijah Wreh Regulatory Affairs Manager Phone: (440) 329-6840 Email: ewreh@invacare.com

MANUFACTURER:	Invacare Corporation 1200 Taylor Street Elyria, Ohio 44035

DATE PREPARED per 21 CFR 807.92(a)(1):	March 19, 2021

Device Information per 21 CFR 807.92(a)(2)

NAME OF SUBJECT DEVICE:	Invacare® AVIVA Storm RX Power Wheelchair

COMMON/USUAL NAME:	Power Wheelchair

CLASSIFICATION NAME:	Powered Wheelchair [21 CFR §890.3860]

REGULATORY CLASS:	2

PRODUCT CODE:	ITI: Wheelchair, Mechanical

PREDICATE DEVICES:	Primary: Invacare AVIVA FX Power Wheelchair (K192216) No reference devices were used in this submission.

Device Description per 21 CFR 808.92(a)(4)

The subject device is a rearward drive wheel version substantially equivalent to the previously cleared forward drive wheel Invacare® AVIVA FX Power Wheelchair (K192216) with LiNX Electronics and Ultra Low Maxx Seating System. The subject device version consists of the following changes:

- Rearward drive wheel placement
- Modification to suspension system
- Modification to battery box design and seat interface brackets
- Minor changes to mechanical components such as new rims and colors

The Invacare® AVIVA Storm RX Power Wheelchair is a 24V DC system, motor-driven wheelchair, utilizing the predicate device LiNX® control system. The subject device consists of a rigid or "non-folding" type power wheelchair base with rearward drive wheel placement with two (2) casters in the front and two anti-tippers in the rear. It is powered by two 12-volt DC batteries and two 4-pole single stage drive motors.

Intended Use per 21 CFR 807.92(A)(5)

The intended use of the device is to provide mobility and positioning to persons limited to a sitting position.

Indications for Use per FORM FDA 3881

The Invacare® AVIVA Storm RX Power Wheelchair is indicated to provide mobility and positioning to persons limited to a sitting position.

Indications for Use Characteristics Comparison

Both the subject and predicate device share the same Indications for Use and Intended use.

Technological Characteristics Comparison with the predicate device per 21 CFR 807.92(a)(6)

The technological characteristics comparison demonstrates that the subject device is substantially equivalent in intended use, design, materials, and operational principles to 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 are intended to provide mobility and positioning to persons limited to a sitting position. 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, energy source, and other device 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 and to provide mobility and positioning to persons limited to a sitting position.

Summary of the Nonclinical Testing used for Substantial Equivalence

The performance testing, device comparison, and dimensional analysis demonstrate that the subject device components and features are the same or substantially equivalent to the predicate device regarding the following:

- Static Stability
- Dynamic Stability of Electric Wheelchairs
- Effectiveness of Brakes
- Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range
- Dimensions Mass and Maneuvering Space
- Maximum Speed Acceleration and Deceleration of Electric Wheelchairs
- Seating and Wheel Dimensions
- Methods for Static Impact and Fatigue Strengths

- Climatic Tests for Electric Wheelchairs
- Climbing Ability of Electrically Powered Wheelchairs
- Power and Control Systems for Electrically Powered Wheelchairs and Scooters
- Information Disclosure Documentation and Labeling
- Wheeled Mobility Devices for Use as Seats in Motor Vehicles
- Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters and Battery Chargers
- Batteries and chargers for powered wheelchairs
- Software Life Cycle
- Flammability Testing
- Assessment of the Ignitability of Upholstered Furniture – Ignition Source Smoldering Cigarette
- Wireless Coexistence

The data generated from the subject Invacare® AVIVA Storm RX Power Wheelchair design verification test reports support a finding of substantial equivalence regarding the device comparison, dimensional analysis, device specifications, design characteristics and to provide mobility and positioning to persons limited to a sitting position.

Indications for Use Comparison Table

Device	**Subject Device** **Invacare® AVIVA Storm RX Power Wheelchair**	**Predicate Device** **Invacare AVIVA FX Power Wheelchair (K192216)**
Indications for Use	To provide mobility and positioning to persons limited to a sitting position	Same
Intended Use	To provide mobility and positioning to persons limited to a sitting position	Same
Type of Use	Prescription (RX Only)	Same

Design and Technological Characteristics Comparison – Finished Device

Component	Description	Invacare® AVIVA FX Power Wheelchair (K192216) Predicate Device	Invacare® AVIVA Storm RX Power Wheelchair Subject Device
SEATING UltraLow Maxx	**Powered Positioning Configurations**	Fixed, Combinations of Tilt/Recline/Elevate	Combinations of Tilt/Recline
	Seat Widths	16" to 24"	Same
	Seat Depths	16" to 23"	Same
	Back Heights	18" to 25" (tilt) or 20" to 27" (tilt and recline)	Same
	Upholstery	Meshtex, Startex, Spacetex, O-Vinyl, Polyester	Same
	Tilt Range	50º	Same
	Recline Range	168º	Same
	Patient Support Surfaces	Ref subject device 'Essential Equivalence' section	Same
	System Name	LiNX	Same
CONTROL SYSTEM LiNX	**Cables**	Variable cable lengths A range of standard cable lengths available	Same
	System Architecture	Microprocessor Controlled	Same
	Non-Expandable Options	Yes	Same
	Expandable Options	Yes	Same
	Wireless Devices	Bluetooth	Same
	Power Source	24V nominal	Same
	Bus Interface	CAN	Same
	Base Configuration	Forward Drive Wheel Placement	Rearward Drive Wheel Placement
BASE	**Base Width**	24.3"	24.8"
	Base Length	42.7"	33.5"
	Ground Clearance	2.6"	2.8''
	Batteries	(2) 12V Sealed VRLA Gel Batteries	Same
	Braking System	Electro-mechanical Friction Brake	Same

	Drive Wheel Size	14” x 3”	Same
	Incline Capability	9º	Same
	Maximum Speed	5.8mph	Same
	Motors	4-Pole SSD	Same
	Occupant Weight Cap	Up to 300lbs.	Same
	Suspension	Four Bar Linkage Suspension System	Four Bar Linkage Suspension System
		Four Bar Linkage Suspension System (Front Drive Wheel)	Four Bar Linkage Suspension System (Rear Drive Wheel)

Performance Characteristics Comparison – Finished Device

Description	Subject Device Invacare® AVIVA StormRX Power Wheelchair	Predicate Device Invacare AVIVA FX Power Wheelchair (K192216)
Base Configuration	Rear Wheel Drive	Front Wheel Drive
Base Width	24.8”	24.3”
Base Length	33.5”	42.7”
Seat-to-Floor Heights	16.75” 17.25” 18.25” 19.25”	16.75” 17.75” 18.75” 19.75”
Ground Clearance	2.8”	2.6”
Batteries	(2) 12V Sealed VRLA Gel Batteries	(2) 12V Sealed VRLA Gel Batteries
Braking System	Electro-mechanical Friction Brake	Electro-mechanical Friction Brake
Castor Size	8” x 2.5”	8” x 2.5”
Control System	LiNX	LiNX
Drive Wheel Size	14” x 3”	14” x 3”
Incline Capability	9°	9°
Maximum Speed	5.8 mph	5.8 mph
Motors	4-Pole SSD	4-Pole SSD
Maximum Weight Bearing Capacity	300lbs.	300lbs.
Range	>12 miles	>12 miles
Suspension	Four Bar Linkage Independent Suspension System (Rear Drive Wheel)	Four Bar Linkage Independent Suspension System (Front Drive Wheel)

LiNX® Components and Accessories Specifications

LiNX Control System – Modules	Description	AVIVA Storm RX	AVIVA FX	Wireless Technology	Impact to Safety and Effectiveness
Primary Driver Controls	Drive Only Remote	Yes	Yes	Bluetooth LE Wireless: Diagnostics	The versions are the same.
	Remotes with LED Display	Yes	Yes	Bluetooth LE Wireless: Diagnostics	The versions are the same.
	Rehabilitation Remote with Colour LCD Display and Touch	Yes	Yes	Bluetooth LE Wireless: Mouse Mover and Diagnostics	The versions are the same.
Alternative Driver Controls (LiNX)	Compact Remote	Yes	Yes	Bluetooth LE Wireless: Mouse Mover and Diagnostics	The versions are the same. .
	Sip 'N' Puff (SNP)	Yes	Yes	No Wireless	
	Attendant Driver Control	Yes	Yes	No Wireless	
		Yes	Yes	No Wireless	
Power Modules	120A, Dual Motor, Power Controller with Lights and 2 Actuator Channels	Yes	Yes	No Wireless	The versions are the same.
Actuator Modules	Actuator Controls only modules: 4 Channel	Yes	Yes		
Stability Control	G-Trac / Gyro	Yes	Yes	No Wireless	The versions are the same.
Programming tool	LAK: LiNX Access Key	Yes	Yes	Bluetooth LE Wireless: Remote Programming	
Switch Input Module	Module used to add separate switched for Power on/ off when used with REM 215/216	Yes – The difference is that the switch input module adds wired remote on/off capability.	No	No Wireless	*Differences

LiNX Control System – Modules	Description	AVIVA Storm RX	AVIVA FX	Wireless Technology	Impact to Safety and Effectiveness
Environmental Control Module	Environmental Control module used for off-chair control of various devices	Yes	Yes	No Wireless	The versions are the same.
Switch Interface Module	Switch Interface Module	Yes – The difference is the switch module is a junction box.	No	No Wireless	*Differences
Light Module	Interface to LED lights on Storm RX chair	Yes – The difference is low voltage power supply for LED light.	No	No Wireless	*Differences
USB Charge Port	Allows charging of Smart pone via USB	Yes	Yes	No Wireless	The versions are the same.
Enhanced DLX-IN500 Input Module	Sip 'N' Puff (SNP)	Yes – Same as the regular DLX-IN500 input module, but the difference is that the firmware was updated.	Yes	No Wireless	*Differences

*Differences: Differences between the subject device features and the previously cleared predicate device do not raise new issues of safety or effectiveness.

Performance Data

Non-Clinical Test per 21 CFR 807.92(b)(1)

International Organization of Standardization (ISO) testing, California Technical (CAL), American National Standards Institute (ANSI) and European (EN) standards testing were performed to demonstrate that the subject Invacare® AVIVA Storm RX Power Wheelchair meet the performance requirements and is substantially equivalent to the predicate device identified throughout this submission and do not raise questions of safety and effectiveness.

Test Standard	Test Description
ISO 7176-1:2014	Wheelchairs Part 1: Determination of Static Stability
ISO 7176-2:2017	Wheelchairs Part 2: Determination of Dynamic Stability of Electrically Powered Wheelchairs
ISO 7176-3:2012	Wheelchairs Part 3: Determination of Effectiveness of Brakes
ISO 7176-4:2008	Wheelchairs Part 4: Energy Consumption of Electrical Wheelchairs and Scooters for Determination of Theoretical Distance Range
ISO 7176-5:2008	Wheelchairs Part 5: Determination of Dimensions, Mass and Maneuvering Space
ISO 7176-6:2018	Wheelchairs Part 6: Determination of Maximum Speed, Acceleration and Deceleration of Electric Wheelchairs
ISO 7176-7:1998	Wheelchairs Part 7: Measurement of Seating and Wheel Dimensions
ISO 7176-8:2014	Wheelchairs Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
ISO 7176-9:2009	Wheelchairs Part 9: Climatic Tests for Electric Wheelchairs
ISO 7176-10:2008	Wheelchairs Part 10: Determination of Obstacle Climbing Ability of Electrically Powered Wheelchairs
ISO 7176-11:2012	Wheelchairs Part 11: Test Dummies
ISO 7176-13:1989	Wheelchairs Part 13: Determination of Coefficient of Friction of Test Surface
ISO 7176-14:2008	Wheelchairs Part 14: Power and Control Systems for Electrically Powered Wheelchairs and Scooters – Requirements and Test Methods
ISO 7176-15:1996	Wheelchairs Part 15: Requirements for Information Disclosure, Documentation and Labeling
ISO 7176-16:2012	Wheelchairs Part 16: Resistance to Ignition of Postural Support Devices
ISO 7176-19	Wheelchairs Part 19: Wheeled Mobility Devices for use as Seats in Motor Vehicles
ISO 7176-21:2008	Wheelchairs Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22:2014	Wheelchairs Part 22: Set-up Procedures
ISO 7176-25:2013	Wheelchairs Part 25: Batteries and chargers for powered wheelchairs
IEC 62304:2006	Medical Device Software – Software Life Cycle
ANSI C63.27:2017	American National Standard for Evaluation of Wireless Coexistence

Performance Data Conclusions per 21 CFR 807.92(b)(3)

The subject device utilizes the same intended use, same material composition, and similar technological characteristics as the predicate device. The non-clinical laboratory 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.