December 11, 2018

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

Re: K182946
Trade/Device Name: Invacare TDX SPV2-HD with Captain's Seat
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 22, 2018
Received: October 23, 2018

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 Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182946

Device Name
Invacare® TDX® SP2-HD with Captain's Seat

Indications for Use *(Describe)*
The indication for use of the Invacare® TDX® SP2-HD with Captain's Seat is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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
1200 Taylor Street
Elyria, OH 44035

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

December 10, 2018

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

Name of Device: Invacare® TDX® SP2-HD with Captain's Seat

Common or Usual Name: Wheelchair, Powered

Classification Name: Powered Wheelchair 21 CFR § 890.3860

Regulatory Class: 2

Product Code: ITI

PREDICATE DEVICE: Invacare® TDX® SP2 Power Wheelchair (K170507)

Patient Population: Adult Patient Only

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

The subject device is an update to the existing previously cleared Invacare® TDX® SP2 Power Wheelchair (K170507) with LiNX Electronics and Ultra Low Maxx Seating System. The updated subject version of the Invacare® TDX® SP2 Power Wheelchair has the following changes:

- Increase in the weight capacity of the previously cleared device from 300 lb to 450 lb.

Model Number	Description
TDXSP2V-HD	Invacare® TDX® SP2-HD with Captain's Seat

Invacare® TDX® SP2 Power Wheelchair is a battery-powered, motor-driven powered wheelchair, controlled by the LiNX® control system with enhanced suspension and additional back, arm and leg rest types. The subject device is a rigid or "non-folding" type power wheelchair base with center-wheel drive capability, two casters in the rear and two casters in the front. It is powered by two 12-volt DC batteries and two 4-pole single stage drive motors. No new accessories were added to the new device.

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 indication for use of the Invacare® TDX® SP2-HD with Captain's Seat is to provide mobility and positioning to persons limited to a sitting position.

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 in regard to provide mobility and positioning to persons limited to a sitting position.

The subject device and predicate device are battery powered, motor driven, rigid, non-folding type power wheelchairs with a micro-processor controlled electronic control systems, and non-powered and powered seating.

The subject device has fixed non-powered and elevate seating systems that are similar to the previously cleared Invacare® TDX® SP2 Power Wheelchair (K170507).

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 design verification and validation testing, device comparison, and dimensional analysis demonstrates that the subject device components are substantially equivalent to the predicate device in regard to the following:

The data generated from the subject device design verification and validation test reports support a finding of substantial equivalence regarding device comparison, wireless capability and coexistence, dimensional analysis, device specifications, and design characteristics.

Indications for Use (IFU) Comparison Table

Description	Subject Device Invacare® TDX® SP2-HD with Captain's Seat	Predicate Device Invacare® TDX® SP2 Power Wheelchair
510(k) Number	Pending Submission	K170507
Indications for Use	The indication for use of the Invacare® TDX® SP2 Power Wheelchair is to provide mobility and positioning to persons limited to a sitting position.	The indication for use of the Invacare® TDX® SP2 Power Wheelchair is to provide mobility and positioning to persons limited to a sitting position.

Design Characteristics Comparison – Finished Medical Device

Description	Subject Device Invacare® TDX® SP2-HD with Captain's Seat	Predicate Device Invacare® TDX® SP2 Power Wheelchair
Base Configuration	Centre Wheel Drive	Centre Wheel Drive
Suspension	Enhanced SureStep® Suspension	Enhanced SureStep® Suspension
Stability Lock	Locking gas cylinder	Locking gas cylinder
Speed	5mph	5mph or 5.8mph
Braking System	Electro-mechanical Friction Brake	Electro-mechanical Friction Brake
Range	GP24 Batteries > 20.7 miles	22NF Batteries > 13.7 miles OR GP24 Batteries > 20.7 miles
Weight Capacity	450lb.	300lb.
Length (without leg rests)	31.5" to 45.3" (depending on seat configuration)	31.5" to 45.3" (depending on seat configuration)
Base Width	25.5"	24" or 25.5" (depending on battery type)
Incline Capability	9º	9º
Total Weight (seat and base)	291-450lbs. (depending on seat configuration)	291-450lbs. (depending on seat configuration)
Obstacle Climbing	Forward 2.76" AND Reverse 0.79"	Forward 2.95" AND Reverse 0.95"
Drive Wheel Frame Material	Aluminum	Aluminum
Transport Option	Brackets bolt on frame	Brackets bolt on frame

Design Characteristics Comparison – Seating System

Description	Subject Device	Predicate Device
	Invacare® TDX® SP2-HD with Captain's Seat	Invacare® TDX® SP2 Power Wheelchair (K170507)
Seat Types	Fixed, Elevate	Fixed, Tilt/Recline/Elevate, Tilt/Recline, Recline, Elevate, Tilt/Elevate, Tilt Only.
Seat Widths	22" to 24"	16" to 24"
Seat Depths	18" to 22"	16" to 23"
Back Heights	18.5"	18" to 25" (tilt only) OR 20" to 27" (tilt and recline)
Upholstery	Vinyl	Meshtex, Startex, Spacetex, O-Vinyl, Polyester
Elevating Seat Range	10"	12"
Tilt Range	N/A	50º
Recline Range	117º	168º

POWER BASE SUBSTANTIAL EQUIVALENCE TABLE

Description	Subject Device Invacare® TDX® SP2-HD with Captain's Seat (Pending)	Predicate Device Invacare® TDX® SP2 Power Wheelchair (K170507)
Base Configuration	Centre Wheel Drive	Centre Wheel Drive
Suspension	Enhanced SureStep® Suspension	Enhanced SureStep® Suspension
Stability Lock	Locking gas cylinder	Locking gas cylinder
Stability Lock Mechanism	Internal locking valve mechanism in gas cylinder	Internal locking valve mechanism in gas cylinder
Stability Lock Side Dependency	Both sides lock/unlock together	Both sides lock/unlock together
Motors	4-Pole SSD	4-Pole SSD
Motor Voltage	24V nominal	24V nominal
Motor Power	24V DC/324W (@13.5Amps)	24V DC/324W (@13.5Amps)
Speed	5mph	5mph, or 5.8mph
Number of Batteries	2	2
Battery Types	GP24	22NF OR GP24
Battery Chemistry	Sealed VRLA Gel Batteries	Sealed VRLA Gel Batteries
Battery Operating Voltage	24V nominal (2 * 12V)	24V nominal (2 * 12V)
Battery Amp-Hour Rating	GP24 = 63amp-hrs (C5)	22NF = 43.2amp-hrs (C5) GP24 = 63amp-hrs (C5)
Battery Weight	GP24 = 52lbs.	22NF = 37lbs. GP24 = 52lbs.

Description	Subject Device Invacare® TDX® SP2-HD with Captain's Seat (Pending)	Predicate Device Invacare® TDX® SP2 Power Wheelchair (K170507)
Battery Chargers	8-amp off board charger (110V)	8-amp off board charger (110V)
Braking System	Electro-mechanical Friction Brake	Electro-mechanical Friction Brake
Range	GP24 Batteries > 20.7 miles	22NF Batteries > 13.7 miles OR GP24 Batteries > 20.7 miles
Stopping Distance	45.7" to 69.3" (depending on chair configuration)	45.7" to 69.3" (depending on chair configuration)
Weight Capacity	450lbs.	300lbs.
Length (without leg rests)	31.5" to 55.4"	31.5" to 55.4"
Base Width	25.5"	24" OR 25.5" (depending on battery type)
Front Forks	Single OR double sided	Single OR double sided
Tires	Black gel tires. Foam filled OR pneumatic	Black gel tires. Foam filled OR pneumatic
Drive Wheel Size	14" x 3"	14" x 3"
Castor Size	6" x 2"	6" x 2"
Front Castor Force	Applied by proportional force gas spring	Applied by proportional force gas spring
Damping on Front Swing Arm	Gas spring has damping	Gas spring has damping
Incline Capability	9º	9º
Turning Diameter	50.4" to 65.4" (depending on seat configuration)	50.4" to 65.4" (depending on seat configuration)
Base Weight (with batteries)	264lbs (GP24 Batteries)	264lbs (GP24 Batteries)
Total Weight (seat and base)	291 to 450lbs. (depending on seat configuration)	291 to 450lbs. (depending on seat configuration)
Ground Clearance	> 2.5"	> 2.5"
Obstacle Climbing	Forward 2.95" AND Reverse 0.98"	Forward 2.95" AND Reverse 0.98"
Motor Gearbox Sound Level	54dBa	54dBa
Drive Wheel Frame Material	Aluminum	Aluminum
Transport Option	Brackets bolt on frame	Brackets bolt on frame

DESIGN VERIFICATION AND VALIDATION TESTING DATA

Design verification and validation testing was performed on the subject device meets 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. The acceptance criteria for the full verification of the design and acceptance criteria for each section of the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) testing standard was met.

Risk Management

Risk Management has been conducted in accordance with *ISO 14971:2007 - Medical Devices - Application of Risk Management to Medical Devices*.

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

Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) testing was performed to demonstrate that the subject Invacare® TDX® SP2-HD with Captain's Seat meets 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.

The following testing was performed according to FDA recognized consensus standards:

- ANSI/RESNA WC-1:2009 Section 1: Determination of Static Stability
- ANSI/RESNA WC-1:2009 Section 2: Determination of Dynamic Stability of electrically Powered Wheelchairs
- ANSI/RESNA WC-1:2009 Section 3: Determination of Effectiveness of Brakes
- ANSI/RESNA WC-2:2009 Section 4: Energy Consumption of Electrically Powered Wheelchairs and Scooters for Determination of Theoretical Distance Range
- ANSI/RESNA WC-1:2009 Section 5: Determination of Dimensions, Mass and Maneuvering Space
- ANSI/RESNA WC-2:2009 Section 6: Determination of Maximum Speed, Acceleration and Deceleration of Electrically Powered Wheelchairs
- ANSI/RESNA WC-1:2009 Section 7: Method of Measurement of Seating and Wheel Dimensions
- ANSI/RESNA WC-1:2009 Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- ANSI/RESNA WC-2:2009 Section 9: Climatic Tests for Electrically Powered Wheelchairs

- ANSI/RESNA WC-2:2009 Section 10: Determination of Obstacle-Climbing Ability of Electrically Powered Wheelchairs
- ANSI/RESNA WC-1:2009 Section 11: Test Dummies
- ANSI/RESNA WC-1:2009 Section 13: Determination of Coefficient of Friction of Test Surfaces
- ANSI/RESNA WC-2:2009 Section 14: Power and Control Systems for Electrically Powered Wheelchairs
- ANSI/RESNA WC-1 :2009 Section 15: Requirements for Information Disclosure, Documentation and Labeling
- ANSI/RESNA WC-1:2009 Section 16: Resistance to Ignition of Upholstered Parts
- ANSI/RESNA WC-4: Section 19: Wheelchairs Used as Seats in Motor Vehicles
- ANSI/RESNA WC-2: 2009 Section 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters
- ISO 7176-25 First Edition 2013 Wheelchairs - Part 25: Batteries and Chargers for Powered Wheelchairs
- ISO 14971:2012 - Medical Devices – Application of Risk Management to Medical Devices

Verification testing demonstrated that the subject Invacare® TDX® SP2-HD with Captain's Seat is substantially equivalent to the marketed predicate device.

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 and validation 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. Therefore, the subject Invacare® TDX® SP2-HD with Captain's Seat accessories are compatible with the previously cleared Invacare® TDX® SP2 Power Wheelchair (K170507) device and demonstrate a basis of substantial equivalence.