DEPARTMENT 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

July 12, 2017

Invacare Corporation
Elijah Wreh
Regulatory Affairs Manager (pre-market)
One Invacare Way
Elyria, Ohio 44035

Re: K170507
Trade/Device Name: Invacare® TDX® SP2 Power Wheelchair
TDXSP2 TDX SP2 with LiNX Electronics, TDXSP2-CG TDX SP2 Base for Single Act. System w/ Ultra Low Maxx, TDXSP2-MCG TDX SP2 Base for Multiple Actuator System w/ Ultra Low Maxx
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 9, 2017
Received: June 12, 2017

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,

Michael J. Hoffmann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170507

Device Name
Invacare® TDX® SP2 Power Wheelchair
TDXSP2 TDX SP2 with LiNX Electronics, TDXSP2-CG TDX SP2 Base for Single Act. System w/ Ultra Low Maxx, TDXSP2-MCG TDX SP2 Base for Multiple Actuator System w/ Ultra Low Maxx

Indications for Use *(Describe)*
The indication for use of the Invacare® TDX® SP2 Power Wheelchair 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.

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510(k) Summary (K170507)

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CONTACT PERSON: Elijah N. Wreh
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Date Prepared: July 12, 2017

DEVICE INFORMATION

Name of Devices: Invacare® TDX® SP2 Power Wheelchair
TDXSP2 TDX SP2 with LiNX Electronics
TDXSP2-CG TDX SP2 Base for Single Act. System w/ Ultra Low Maxx,
TDXSP2-MCG TDX SP2 Base for Multiple Actuator System w/ Ultra Low Maxx

Common or Usual Name: Wheelchair, Powered

Classification Name: Powered Wheelchair 21 CFR § 890.3860

Regulatory Class: II

Product Code: ITI

PRIMARY PREDICATE DEVICE: Invacare® TDX® SP2 Power Wheelchair (K141783)

SECONDARY PREDICATE DEVICE: Modular Power Positioning System (K150574)

REFERENCE DEVICES: F3 Powered Wheelchair (K143180)
F5 Powered Wheelchair (K143014)
Quantum Q6 Edge (K143383)
Modular Power Positioning System (K150574)

DEVICE DESCRIPTION

The subject device is an update to the existing previously cleared Invacare® TDX® SP2 Power Wheelchair (K141783) with the MK6i™ control system and Formula™ CG Seating System. The updated subject version of the Invacare® TDX® SP2 Power Wheelchair has the following changes:

- The LiNX® control system, which incorporates updated software, wireless technology and a touch user interface,
- The Ultra-Low Maxx™ Seating System, and
- Minor changes to mechanical components such as rim inserts and new colours.

Description
TDXSP2 TDX® SP2 with LiNX Electronics
TDXSP2-CG TDX® SP2 Base for Single Actuator System w/ Ultra Low Maxx
TDXSP2-MCG TDX SP2 Base for Multiple Actuator System w/ Ultra Low Maxx

The 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 centre-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.

There are three (3) wireless functions available in the LiNX System. These functions are Mouse Mover, Remote Diagnostics of the Power Wheelchair and Configuration/Programming of the LiNX Control System. The Mouse Mover and Remote Diagnostics of the Power Wheelchair functions are built into all the LiNX Remotes and use a Bluetooth LE wireless connection.

The Mouse Mover function allows the end user of the subject Invacare® TDX® SP2 Power Wheelchair device to operate a standard wireless PC mouse where the joystick or Alternative Driver Control can be used to navigate the cursor on the screen on a PC, tablet or other similar device.

The Remote Diagnostics of the Power Wheelchair function send specific diagnostic information relevant to the status of the wheelchair electronics to an Apple iOS device.

The Configuration/Programming of the LiNX Control System requires a separate programming access key (LiNX Access Key: LAK) that plugs into the LiNX Control System via one of its remotes (Joysticks) and communicates over a Bluetooth connection. This is used for remote programming of the LiNX Control system.

Each accessory connects to the LiNX Control system either directly by connecting to the LiNX communication bus (direct access) or indirectly by connecting to an Input module (indirect access).

The associated models and accessories and capabilities include:

- Invacare® TDX SP2™ with Motion Concepts Ultra Low Maxx Power Positioning
- Primary Driver Controls (Bluetooth LE Wireless Capable: Mouse Mover and Diagnostics)
    - Export data to application
- Attendant Driver Controls (No Wireless)
    - Provide a simple interface for the wheelchair attendant using a LiNX System
    - Control of actuators through the joystick
- Alternative Driver Controls (Bluetooth LE Wireless Capable: Mouse Mover)
    - Has a compact, low-profile design, and is a secondary remote module designed to provide a simple interface for the wheelchair occupant using a LiNX Control System
    - Low force joystick option to improve control for those with low muscle strength
    - Controls mouse movement
- Display Modules (Bluetooth LE Wireless Capable: Mouse Mover and Diagnostics)
    - Provides a relocatable user interface for use for alternative driver controls
    - Provides the same level of functionality as the enhanced rehabilitation primary display except for the joystick
- Actuator Control (No Wireless)
    - The Actuator Control Module has an in-built accelerometer used to provide angular feedback of the seating position which is in turn used to limit driving capability
    - 2-Channel Actuator Module
    - 4-Channel Actuator Module
- Power Modules (No Wireless)
    - Process the user commands issued via the joystick or alternative drive control and control the motion of the wheelchair by varying the amount of power supplied to the left and right wheelchair motors
- Stability Control (No Wireless)
    - G-Trac / Gyro
- Input Module with Integrated Sip-n-Puff (No Wireless)
    - Sip and puff nozzle
    - Jack input (stereo)

    - 2 x LiNX bus connectors
    - Activity indicator displaying input demands
- USB Charger Module (No Wireless)
    - The USB charger module includes protection mechanisms for short circuit and over-current
- 4-way expansion block (No Wireless)
    - harness for expandable systems
- Atom Proton Head Array (Bluetooth LE Wireless: Mouse Mover)
    - Direct access
- MEC mini joystick (Bluetooth LE Wireless: Mouse Mover)
    - Direct access
- Extremity control (Bluetooth LE Wireless: Mouse Mover)
    - Direct access
- Compact, Single Switch (Bluetooth LE Wireless: Mouse Mover)
    - Indirect Access (via input module)
- Compact (No Wireless)
    - Indirect Access (via input module)
- 4-Switch Proximity (Bluetooth LE Wireless: Mouse Mover)
    - Indirect Access (via input module)
- Sip-n-Puff Head Array (No Wireless)
    - Indirect Access (via input module)
- Wireless double switch receiver (Bluetooth LE Wireless: Mouse Mover)
    - Indirect Access (via input module)
- Wireless triple switch receiver (Bluetooth LE Wireless: Mouse Mover)
- Wireless mouse emulator (Bluetooth LE Wireless: Mouse Mover)
- LiNX Access Key (LAK: Bluetooth Wireless: Remote Programming)

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.

INDICATIONS FOR USE (IFU) COMPARISON

The Indications for Use statement for the subject device is the same as the secondary predicate device, the Modular Power Positioning System cleared under K150574 Indications for Use statement, which is to provide "positioning to individuals without adequate upper-body stability." The determination was made based Section 513(i)(1)(E)(i) of the FD&C Act. The seating system for the subject Invacare® TDX® SP2 Power Wheelchair device is Modular Power Positioning System (K150574) which is indicated for positioning functions that are offered on the subject device and is designed to help patients without adequate upper-body

stability to be tilted and allow gravity to hold them in position. The subject device positioning also help the patients to reach higher elevations in a seated position, increasing their range of motion and accessibility.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY and SECONDARY PREDICATE DEVICES and REFERENCE DEVICES

The device comparison showed that the subject device is substantially equivalent in intended use, design, materials, and operational principles to the previously cleared primary and secondary predicate devices and/or specified reference devices below in regards to provide mobility and positioning to persons limited to a sitting position.

- Invacare® TDX® SP2 Power Wheelchair (K141783)
- F3 Powered Wheelchair (K143180)
- F5 Powered Wheelchair (K143014)
- Quantum Q6 Edge (K143383)
- Modular Power Positioning System (K150574)

The subject device, predicate device and all reference devices excluding the secondary predicate device Motion Concepts Modular Power Positioning System are battery powered, motor driven, rigid, non-folding type power wheelchairs with a micro-processor controlled electronic control systems, non-powered and powered seating and a selection of alternative drive controls.

The subject device has the same seating system as previously cleared secondary predicate Module Power Positioning System device.

The secondary predicate device and the reference devices were chosen to demonstrate substantial equivalence for the following components and features in the subject device:

- LiNX® Control System
- Power Wheelchair Base
- Power Wheelchair Seating

BASIS OF SUBSTANTIAL EQUIVALENCE

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 subject device components are as safe and effective as the predicate and reference devices and do not raise different questions of safety and effectiveness. The differences between the subject device features and the previously cleared predicate and reference devices do not raise new issues of safety or effectiveness.

The performance testing, device comparison, and dimensional analysis demonstrates that the subject device components are substantially equivalent to the predicate and reference devices in regards to 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 Manoeuvring Space
- Maximum Speed Acceleration and Deceleration of Electric Wheelchairs
- 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
- Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters and Battery Chargers
- Software Life Cycle
- Additional Requirements for Wheelchairs (including scooters) with Electrical Systems
- Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters
- Flammability Testing
- Assessment of the Ignitability of Upholstered Furniture – Ignition Source Smouldering Cigarette
- Assessment of the Ignitability of upholstered Furniture – Ignition Source Match Flame Equivalent
- Wireless Coexistence

The data generated from the subject Invacare® TDX® SP2 Power Wheelchair Design Verification test report supports a finding of substantial equivalence in regards to 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 (IFU) Comparison Table

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair	Primary Predicate Device	Secondary Predicate Device
		Invacare® TDX® SP2 Power Wheelchair	Modular Power Positioning System
510(k) Number	Pending Submission	K141783	K150574
Indications for Use	To provide mobility and positioning to persons limited to a sitting position	To provide mobility to persons limited to a sitting position.	The Modular Power Positioning system is appropriate for use by any individual who drives a power wheelchair and who desires or requires a change of position without having to utilize the services of an attendant. Needs for position changes include: - All positioning benefits associated with the tilt/recline product: Comfort: As with any individual, able-bodied or disabled, changes in position are necessary to maintain a state of comfort. Positioning: Individuals without adequate upper-body stability can be tilted to allow gravity to hold them in position. Pressure Relief or Reduction: Individuals who wish, from time to time, to redistribute pressure from one area of the body to another, can do so by tilting and/or reclining. By changing the individual's orientation in space, pressures caused by gravity will shift. - Positioning/Versatility: Individuals are able to reach higher elevations in a seated position, increasing their range of motion and accessibility. Motion Concepts makes no claims as to the therapeutic effectiveness of the products. Our only claims relate to the ability of the products to provide safe and reliable powered repositioning on the equipment onto which they are installed.

Design Characteristics Comparison – Finished Medical Device

Description	Subject Device TDX® SP2	Primary Predicate Device TDX® SP2
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 or 5.8mph	5.8mph
Braking System	Electro-mechanical Friction Brake	Electro-mechanical Friction Brake
Range	22NF Batteries > 13.7 miles OR GP24 Batteries > 20.7 miles	22NF Batteries > 12 miles OR GP24 Batteries > 15 miles
Weight Capacity	300lbs.	300lbs. (Adult seating) 165lbs. (Junior seating)
Length (without leg rests)	31.5" to 45.3" (depending on seat configuration)	35.5"
Base Width	24" OR 25.5" (depending on battery type)	24" OR 25.5" (depending on battery type)
Incline Capability	9º	9º
Total Weight (seat and base)	291-450lbs. (depending on seat configuration)	291-425lbs. (depending on seat configuration)
Obstacle Climbing	Forward 2.95" AND Reverse 0.95"	Forward 2.76" AND Reverse 0.98"
Drive Wheel Frame Material	Aluminum	Aluminum
Transport Option	Brackets bolt on frame	Brackets bolt on frame

Secondary and Reference Predicate Devices

Subject Device	Component or Sub-Assembly	Secondary Predicate Device and Reference Devices		510(k) Clearance Code/s	Clearance Date/s
Invacare TDX® SP2 Power Wheelchair	TDX® SP2 Power Base	Invacare® TDX® SP2 Power Wheelchair		K141783	1st September 2015
	Ultra-Low Maxx Seating (Secondary Predicate Device)	Motion Concepts Modular Power Positioning System		K150574	30th June 2015
	LiNX® Control System	Invacare TDX® SP2	Mk6i	K141783	1st September 2015
		Permobil F3	R-Net	K143180	27th March 2015
		Permobil F5	R-Net	K143014	25th March 2015
		Quantum Q6 Edge EM	Q-Logic2	K143383	23rd July 2015

Design Characteristics Comparison – LiNX® Electronics

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair	Primary Predicate Device Invacare® TDX® SP2 Power Wheelchair (K141783)	Reference Devices	
			F3 Powered Wheelchair & F5 Powered Wheelchair	Quantum Q6 Edge
System Name	LiNX	MK6i	R-Net	Q-Logic2
Cables	Variable cable lengths A range of standard cable lengths available	Primarily fixed length flying leads, connecting at a single "star point"	Variable cable lengths A range of standard cable lengths available	Variable cable lengths A range of standard cable lengths available
System Architecture	Microprocessor Controlled	Microprocessor Controlled	Microprocessor Controlled	Microprocessor Controlled
Non-Expandable Options	Yes	Yes	Yes	Yes
Expandable Options	Yes	Yes	Yes	Yes
Wireless Devices	Bluetooth	None	Bluetooth Infra-Red	Bluetooth Infra-Red
Power Source	24V nominal	24V nominal	24V nominal	24V nominal
Bus Interface	CAN	Mixed CAN & 2-Wire Serial	CAN	CAN

Design Characteristics Comparison – Seating

Description	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Invacare® TDX® SP2 Power Wheelchair	Invacare® TDX® SP2 Power Wheelchair (K141783) (Formula CG)	Motion Concepts Modular Power Positioning System (K150574)
Seat Types	Fixed, Tilt/Recline/Elevate, Tilt/Recline, Recline, Elevate, Tilt/Elevate, Tilt Only.	ADJASBA, ADJRECL, Formula TRE, Tilt/Recline/Elevate, Tilt/Recline, Recline, TRE, Elevate, Tilt/ Elevate	Fixed, Tilt/Recline/Elevate, Tilt/Recline, Recline, Elevate, Tilt/Elevate, Tilt Only
Seat Widths	16" to 24"	12" to 24"	15" to 24"
Seat Depths	16" to 23"	12" to 22"	15" to 22"
Back Heights	18" to 25" (tilt only) OR 20" to 27" (tilt and recline)	12" to 28"	18" to 30"
Upholstery	Meshtex, Startex, Spacetex, O-Vinyl, Polyester	Cloth & Vinyl	Meshtex, Startex, Spacetex, O-Vinyl, Polyester
Elevating Seat Range	12"	7"	12"
Tilt Range	50º	Not Specified	50º
Recline Range	168º	Not Specified	168º

POWER BASE SUBSTANTIAL EQUIVALENCE TABLE

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair (Pending)	Primary Predicate Device Invacare® TDX® SP2 Power Wheelchair (K141783)
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, or 5.8mph	5.8mph
Number of Batteries	2	2
Battery Types	22NF OR 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	22NF = 43.2amp-hrs (C5) GP24 = 63amp-hrs (C5)	22NF = 43.2amp-hrs GP24 = 63amp-hrs
Battery Weight	22NF = 37lbs. GP24 = 52lbs.	22NF = 37lbs. GP24 = 52lbs.
Battery Chargers	8-amp off board charger (110V)	8-amp off board charger (110V or 220V)
Braking System	Electro-mechanical Friction Brake	Electro-mechanical Friction Brake
Range	22NF Batteries > 13.7 miles OR GP24 Batteries > 20.7 miles	22NF Batteries > 12 miles OR GP24 Batteries > 15 miles
Stopping Distance	45.7” to 69.3” (depending on chair configuration)	74.8” to 102.4” (depending on chair configuration)
Weight Capacity	300lbs.	300lbs. (Adult seating) 165lbs. (Junior seating)
Length (without leg rests)	31.5” to 55.4”	35.5”
Base Width	24” OR 25.5” (depending on battery type)	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	Pneumatic OR gel/foam filled flat free tires.
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

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair (Pending)	Primary Predicate Device Invacare® TDX® SP2 Power Wheelchair (K141783)
Turning Diameter	50.4" to 65.4" (depending on seat configuration)	< 46"
Base Weight (with batteries)	264lbs (GP24 Batteries)	264lbs (GP24 Batteries)
Total Weight (seat and base)	291 to 450lbs. (depending on seat configuration)	291 to 425lbs. (depending on seat configuration)
Ground Clearance	> 2.5"	3"
Obstacle Climbing	Forward 2.95" AND Reverse 0.98"	Forward 2.76" AND Reverse 0.98"
Motor Gearbox Sound Level	54dBa	58dBa
Drive Wheel Frame Material	Aluminum	Aluminum
Transport Option	Brackets bolt on frame	Brackets bolt on frame

General Comparison of the Performance Characteristics Associated with the Control System

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair (Pending)	Primary Predicate Device Invacare® TDX® SP2 Power Wheelchair (K141783)	Reference Devices	
			Permobil F3 & F5 (K143180 & K143014)	Quantum Q6 Edge (K143383)
Cables	Variable cable lengths A range of standard cable lengths available	Primarily fixed length flying leads, connecting at a single "star point"	Variable cable lengths A range of standard cable lengths available	Variable cable lengths A range of standard cable lengths available
System Architecture	Microprocessor Controlled	Microprocessor Controlled	Microprocessor Controlled	Microprocessor Controlled
Non-Expandable Options	Yes	Yes	Yes	Yes
Expandable Options	Yes	Yes	Yes	Yes
Wireless Devices	Bluetooth	None	Bluetooth Infra-Red	Bluetooth Infra-Red
Power Source	24V nominal	24V nominal	24V nominal	24V nominal
Bus Interface	CAN	Mixed CAN & 2-Wire Serial	CAN	CAN

Comparison of the Performance Characteristics Associated with the Drive Only Primary Remotes

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair (Pending)	Primary Predicate Device Invacare® TDX® SP2 Power Wheelchair (K141783)
	REM110	Mk6i SPJ
Mounting	2 x M5 screws suitable for both tube and plate.	4 x M5 screws suitable for both tube and plate.
Connector Type	Direct	Direct
User Display	LED	LED
Joystick	Magnetic	Inductive
On/Off Button	Yes	Yes
Horn	Yes	Yes
Speed Selection	Speed dial.	Speed up and speed down buttons.
Number of Drive Functions	1	1
Battery Gauge	5 x LED's	8 x LED's
Charger Port	XLR	XLR
Status Indicator	Power button 'flash codes'.	Service LED.
Remote Diagnostics	Yes. Built-in Bluetooth connection.	No.

Comparison of the Performance Characteristics Associated with the Enhanced Rehabilitation Primary Remotes

Description	Subject Device Invacare® TDX® SP2 Power Wheelchair (Pending)	Primary Predicate Device Invacare® TDX® SP2 Power Wheelchair (K141783)	Reference Devices	
			Permobil F3 & F5 (K143180 & K143014)	Quantum Q6 Edge (K143383)
	REM400	Mk6i-MPJC	R-Net CJSM2	Q-Logic2 EX Joystick
Mounting	2 x M5 screws suitable for both tube and plate.	4 x M5 screws suitable for both tube and plate.	2 x M5 screws suitable for both tube and plate.	4 x 10-32 screws suitable for both tube and plate.
Connection	Direct	Flying Lead	Flying Lead	Flying Lead
User Display	LCD – colour.	LCD – colour.	LCD – colour.	LDC – colour.
Viewable LCD Size	49 x 74mm	46 x 35mm	53 x 71mm	44 x 57mm
Joystick	Magnetic	Inductive	Magnetic	*Not Available*
Text & Graphics	Icons & translations. Customisable.	Icon based with text.	Icon & translations. Multi-language support	Icon and translations. 5 languages.
Touch Interface	Yes – capacitive	No	No	No
On/Off Button	Yes	Yes	Yes	Yes
Horn	Yes	No	Yes	Yes
Mode/Function	Button or Touch	Button	Toggle	Button
Programmable Multi-Function Keys	2 x Configurable	No	4 x Configurable	2 x Configurable
Jack Sockets	2 x Stereo.	1 x Mono * 1 x Stereo	2 x Mono	2 x Mono
Speed Selection	Virtual speed dial operated by touch.	Speed dial.	Virtual speed dial operated by toggles.	Speed dial.
Speed Indication	Yes	Yes	Yes	Yes
Number of Drive Functions	36	4	8	5
Battery Gauge	Bar on LCD (continuous)	Battery icon with fill level on LCD (6 discrete segments)	Bar on LCD (10 discrete segments)	Battery icon with fill level on LCD (continuous)
Seating Control	Up to 8 actuators	Up to 6 actuators	Up to 8 actuators	Up to 6 actuators
Lighting Control	Yes	No	Yes	Yes
Real Time Clock	Yes	Yes	Yes	Yes
Charger Port	XLR	XLR	XLR	XLR
Status Indicator	Error codes on display with supporting icons. Additional LED flash codes for faulty LCD.	Error codes on display with brief description.	Error codes with brief description on display with LED for faulty LCD.	Error codes with brief description on display
Mouse Mover	Yes. Built-in Bluetooth connection.	No	Yes. Built-in Bluetooth connection.	Yes. Built-in Bluetooth connection.
Remote Diagnostics	Yes. Built-in Bluetooth connection.	No	No	No

Comparison of the Performance Characteristics Associated with the Ultra-Low Maxx Seating System

Description	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Invacare® TDX® SP2 Power Wheelchair (Pending)	Invacare® TDX® SP2 Power Wheelchair – (CG Formula) (K141783)	Modular Power Positioning System (K150574)
Seat Types	Fixed, Tilt/Recline/Elevate, Tilt/Recline, Recline, Elevate, Tilt/Elevate, Tilt Only.	ADJASBA, ADJRECL, Formula TRE, Tilt/Recline/Elevate, Tilt/Recline, Recline, TRE, Elevate, Tilt/ Elevate	Fixed, Tilt/Recline/Elevate, Tilt/Recline, Recline, Elevate, Tilt/Elevate, Tilt Only
Seat Widths	16" to 24"	12" to 24"	15" to 24"
Seat Depths	16" to 23"	12" to 22"	15" to 22"
Back Heights	18" to 25" (tilt only) OR 20" to 27" (tilt and recline)	12" to 28"	18" to 30"
Upholstery	Meshtex, Startex, Spacetex, O-Vinyl, Polyester	Cloth & Vinyl	Meshtex, Startex, Spacetex, O-Vinyl, Polyester
Elevating Seat Range	12"	7"	12"
Tilt Range	50º	Not Specified	50º
Recline Range	168º	Not Specified	168º
Seat Cushion Accessories	Matrx Libra, Matrx PS, Matrx Vi, Matrx Flo-tech Lite and Contour	In-Touch™, Targit™ Cushions, Infinity Cushions, Leg Cutouts, Leg Wedges	Matrx Libra, Matrx PS, Matrx Vi
Back Types	High Back, Matrx PB, Matrx PB Elite, Matrx PB Deep and Matrx PB Elite TR	Contoura™, Conventional, ABS, Back Posts Only, Sectional Rear Uprights, Straight Rear Uprights, 85-105 Degree Adjustment	High Back, Matrx PB, Matrx PB Elite, TRx Rehab Back, Contour
Back and Headrest Accessories	Motion Concepts standard, Elan standard, Elan Occipital, Elan 4-point and Motion Concepts Onyx	Reinforced back upholstery, Personal backs, Stealth Headrests	Stealth, Stealth Nino, MC Auto Style
Arm Types	<u>Tilt Armrests</u> Dual post adjustable, Ultra Rail mounted flip back cantilever Maxx tilt arm <u>Recline Armrests</u> Adjustable, Maxx style cane mounted straight and curved.	Flip Back, Fixed or Adjustable Height and Desk or Full Length	Dual post adjustable height, Seat mounted height and angle adjustable cantilever flip back tilt, Cane mounted height and angle adjustable cantilever flip back, Reclining adjustable height.
Armpads	Modular, Standard, Waterfall, Flat and Ergonomic	Not Specified	Modular, Standard, Waterfall, Flat and Ergonomic
Leg Rest Types	Basic fixed centre mount, Invacare Action fixed swing away receiver, Invacare 70º fixed swing away, LNX powered centre mount, Maxx style powered swing away, Maxx style manual swing away, Heavy duty 70º swing away.	Centre Mount and Swing-Away Styles	LNX Power centre mount platform, TRX Swing away power elevating pivot plus, TRX Pivot Plus manual elevating, TRX HD 70° swing-away footrest, Adjustable 70° to 90° fixed centre mount foot platform.
Leg Rest Accessories	Flip-up foot platform, Individual foot plates for centre mount, Foot plate options for elevating and swing-away, Single foot plate options (adjustable and multi-axis adjustable, Heel loops, Calf panel	Calf Strap, Heel Loops with Ankle Straps, Impact Guards	Not Specified

Description	Subject Device	Primary Predicate Device	Secondary Predicate Device
	Invacare® TDX® SP2 Power Wheelchair (Pending)	Invacare® TDX® SP2 Power Wheelchair – (CG Formula) (K141783)	Modular Power Positioning System (K150574)
Laterals	Matrx standard fixed and offset fixed, Matrx swing away, Matrx Elite swing away, Matrx Offset Elite swing away, Matrx lateral trunk support with fixed mounting, Maxx Style swing-away	Not Specified	Matrx standard fixed and offset fixed, Matrx swing away, Matrx Elite swing away, Matrx Offset Elite swing away, Maxx Style swing-away
Hip Supports	Lateral, Lift-off removable, Maxx style quick release, Swing away removable	Not Specified	Lift-off removable, Maxx style quick release, Swing away removable, Stealth flip down knee support

PERFORMANCE TESTING DATA

International Organization of Standardization (ISO) testing, California Technical (CAL) and European standards (EN 1021-1 and 2) testing were performed to demonstrate that the subject Invacare® TDX® SP2 Power Wheelchair meet 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.

Because the subject Invacare® TDX® SP2 Power Wheelchair is highly configurable Power Wheelchair (PWC), intended to serve a diverse population with unique individual needs, a wide variety of options and accessories have been designed. However, due to the highly customizable nature of the subject device, testing to every possible combination would not be practical. However, every design feature of the subject device was verified. This was accomplished by identifying the specific wheelchair configurations that represent the full range of product permutations. The acceptance criteria for the full verification of the design and acceptance criteria for each section of the standard (ISO 7176) was met.

Risk Management

Risk Management has been conducted in accordance with *ISO 14971:2012 - Medical Devices - Application of Risk Management to Medical Devices.*

Non-Clinical Test

Non-clinical laboratory testing was performed on the subject Invacare® TDX® SP2 Power Wheelchair to determine substantial equivalence. The following testing was performed:

- ISO 7176-1 Third Edition 2014-10-01, Wheelchairs - Part 1: Determination of Static Stability
- ISO 7176-2 Second Edition 2001-06-15, Wheelchairs - Part 2: Determination of Dynamic Stability of Electric Wheelchairs
- ISO 7176-3 Third Edition 2012-12-15, Wheelchairs - Part 3: Determination of Effectiveness of Brakes
- ISO 7176-4 Third Edition 2008-10-01, Wheelchairs - Part 4: Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range
- ISO 7176-5 Second Edition 2008-06-01, Wheelchairs - Part 5: Determination of Overall Dimensions Mass and Manoeuvring Space
- ISO 7176-6 Second Edition 2001-10-01, Wheelchairs - Part 6: Determination of Maximum Speed Acceleration and Deceleration of Electric Wheelchairs

- ISO 7176-7 First Edition 1998-05-15, Wheelchairs - Part 7: Measurement of Seating and Wheel Dimensions
- ISO 7176-8 Second Edition 2014-12-15, Wheelchairs - Part 8: Requirements and Test Methods for Static Impact and Fatigue Strengths
- ISO 7176-9: Third Edition 2009-11-15, Wheelchairs - Part 9: Climatic Tests for Electric Wheelchairs
- ISO 7176-10 Second Edition 2008-11-01, Wheelchairs - Part 10: Determination of Obstacle – Climbing Ability of Electrically Powered Wheelchairs
- ISO 7176-11 Second edition 2012-12-01, Wheelchairs - Part 11: Test Dummies
- ISO 7176-13 First edition 1989-08-01, Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surface
- ISO 7176-14 Second Edition 2008-02-15, Wheelchairs - Part 14: Power and Control Systems for Electrically Powered Wheelchairs and Scooters – Requirements and Test Methods
- ISO 7176-15 First Edition 1996-11-15, Wheelchairs - Part 15: Requirements for Information Disclosure Documentation and Labeling
- ISO 7176-21 Second Edition 2009-04-01, Wheelchairs - Part 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters and Battery Chargers
- ISO 7176-22 Second Edition 2014-09-01, Wheelchairs - Part 22: Set-up Procedures
- ISO 7176-25 First Edition 2013 Wheelchairs - Part 25: Batteries and Chargers for Powered Wheelchairs
- IEC 62304:2006, Medical Device Software – Software Life Cycle
- ANSI / RESNA WC-2:2009, American National Standard for Wheelchairs – Volume 2, Additional Requirements for Wheelchairs (including scooters) with Electrical Systems Section 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters
- CAL117:2013, Section 1: Flammability Testing
- EN 1021-1:2014: Furniture. Assessment of the Ignitability of Upholstered Furniture. Ignition Source Smouldering Cigarette
- EN 1021-2:2014: Furniture. Assessment of the Ignitability of upholstered Furniture. Ignition Source Match Flame Equivalent
- ANSI C63.27 - Wireless Coexistence

Verification Testing demonstrated that the subject Invacare® TDX® SP2 Power Wheelchair is substantially equivalent to the marketed primary and secondary predicate devices and reference devices.

Software Verification Testing

Software Verification Testing was performed to evaluate the functionality of the design, materials, and operational principles of the subject device. Software verification testing was conducted on the subject device as recommended by the FDA's guidance document "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005." and *IEC 62304:2006, Medical Device Software – Software Life Cycle*.

Level of Concern: The Level of Concern for the subject device software is moderate. This determination is based on answering the questions in the FDA Guidance Document "*FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005*." All of the questions related to a Major Level of Concern were answered "No." One question in the Moderate Level of Concern was answered "Yes" because "prior to mitigation of hazards, a failure of the Software Device could result in Minor Injury, either to a patient or to a user of the subject device

Biocompatibility Testing

The biocompatibility evaluation for the subject Invacare® TDX® SP2 Power Wheelchair were 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

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required for this submission.

CONCLUSIONS

The subject device has the same intended use and similar technological characteristics as the predicate devices. The non-clinical laboratory data support the safety and performance of the subject device and demonstrate that the subject device should perform as intended in the specified use conditions. Therefore, the subject Invacare® TDX® SP2 Power Wheelchair is substantially equivalent to the predicate devices identified throughout this submission.