November 14, 2018

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

Re: K181090
Trade/Device Name: Invacare® Solara® 3G and Solara® 3G Spree Manual Wheelchairs
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: August 13, 2018
Received: August 16, 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 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/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)*
K181090

Device Name
Invacare® Solara® 3G and Solara® 3G Spree Manual Wheelchairs

Indications for Use *(Describe)*
The Invacare® Solara® 3G Manual Wheelchair and Invacare® Solara® 3G Spree Manual Wheelchair are intended to provide mobility to adults 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 – K181090

SUBMITTER per 21 CFR 807.92(a)(1)

Invacare Corporation
One Invacare Way
Elyria, OH 44035

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

SECONDARY CONTACT PERSON:
Kevin Malinowski
Senior Quality Engineer
Phone: (440) 329-6179
Email: kmalinowski@invacare.com

MANUFACTURER:
INVAMEX S.DE R.L. DE C.V.
Avenida El Puente S/N
Parque Industrial El Puente Manimex
Reynosa Tamaulipas, Mexico C.P. 88783

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

November 14, 2018

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

Name of Device: Solara® 3G and Solara® 3G Spree Manual Wheelchairs
Common or Usual Name: Wheelchair, Mechanical
Regulation Description: Mechanical Wheelchair
Regulation Number: 21 CFR §890.3850
Review Panel: Physical Medicine
Device Class: 1
Product Code: IOR

PRIMARY PREDICATE DEVICE: Invacare® Solara® Manual Wheelchairs (K984447)

SECONDARY PREDICATE DEVICE: Invacare® Solara® Jr. Manual Wheelchairs (K012370)

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

The Invacare® Solara® 3G Manual Wheelchair is an attendant operated and self-propelled, mechanical wheelchair for adults. The indication for use of the Invacare® Solara® 3G Manual Wheelchair is to provide mobility to adults limited to a sitting position. The indication for use of the Invacare® Solara® 3G Spree Manual Wheelchair is to provide mobility to person limited to a sitting position. These devices are rigid, "non-folding" type wheelchairs that incorporate a solid seating surface (seat pan).

Below is the subject devices weight capacity:

- Invacare® Solara® 3G Manual Wheelchair weight capacity is 300 lbs.
- Invacare® Solara® 3G Manual Wheelchair with Heavy Duty weight capacity is 400 lbs.
- Invacare® Solara® 3G Spree Manual Wheelchair weight capacity is 200 lbs.

Invacare® Solara® 3G and Invacare® Solara® 3G Spree Manual Wheelchair include a "Tilt in Space" feature which allows the seat and back of the wheelchair to be tilted backward. This feature is used for those patients who require a tilt feature for stability, comfort or head control. It also serves as an attendant aid in those situations where the patient needs to be tilted to be fed or receive care. Both predicate devices include the "Tilt in Space" feature.

Both subject devices include a Low Shear Recline Feature which was developed to reduce the amount of shear experienced by the user versus the single-pivot recline system incorporated into the predicate devices.

The associated model and accessories include:

- Invacare® Solara® 3G Manual Wheelchair
  - weight capacity is 300 lbs.
- Invacare® Solara® 3G Manual Wheelchair with Heavy Duty
  - weight capacity is 400 lbs.
- Invacare® Solara® 3G Spree Manual Wheelchair
  - weight capacity is 200 lbs.

- Stealth™ Headrest
- Matrx™ Cushions
- Straps (seat, hook and loop, airline buckle)
- Loops (Heal, Toe)
- Anti-Tippers
- Telescoping Rod

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

The Invacare® Solara® 3G Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.

INDICATIONS FOR USE per FORM FDA 3881

The Invacare® Solara® 3G Manual Wheelchair and Invacare® Solara® 3G Spree Manual Wheelchair are intended to provide mobility to adults limited to a sitting position.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES per 21 CFR 807.92(a)(6)

The device comparison showed that the subject device is substantially equivalent in intended use, design and operational principles to the previously Invacare® Solara® Jr. Manual Wheelchairs (K012370) and Invacare® Solara® Manual Wheelchairs (K984447). The subject device is substantially equivalent to the predicate devices regarding intended use, design, materials, and operational principles to provide mobility to persons limited to a sitting position.

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 subject device components are as safe and effective as the predicate devices and do not raise different questions of safety and effectiveness.

The major frame components for the subject Invacare® Solara® 3G and Invacare® Solara® 3G Spree Manual Wheelchair and the previously cleared Invacare® Solara® Jr. Manual

Wheelchairs (K012370) and Invacare® Solara® Manual Wheelchairs (K984447) are the same. The data generated from the subject device test report supports a finding of substantial equivalence regarding the device comparison, dimensional analysis, device specifications, design characteristics and to provide mobility to persons limited to a sitting position.

The difference in weight capacity between the subject Invacare® Solara® 3G and Invacare® Solara® 3G Spree Manual Wheelchair and the previously cleared Invacare® Solara® Jr. Manual Wheelchairs (K012370) and Invacare® Solara® Manual Wheelchairs (K984447) do not raise new issues of safety or effectiveness.

Design Comparison – Invacare® Solara® 3G Manual Wheelchair with 300 lbs Weight Capacity

Device	Invacare® Solara® 3G Manual Wheelchair	Invacare® Solara® Manual Wheelchairs
510(k) Number	Subject Device Pending Submission	Predicate Device (K984447)
Intended Use	The Invacare® Solara® 3G Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.	Intended to provide mobility to persons limited to a sitting position.
Indications for Use	The Invacare® Solara® 3G Manual Wheelchair and Invacare® Solara® 3G Spree Manual Wheelchair are intended to provide mobility to adults limited to a sitting position.	To provide mobility to adults limited to a sitting position
Design		
Weight Limit	300 lbs.	250 lbs. 300 lbs. (With Heavy Duty Package)
Seat Width	12”-24”	14”-20”
Seat Depth	12”-22”	14”-18”
Back Style	Standard Back Cane [1]Low Sheer Recline (not available on 400 lbs. weight limit wheelchair)	Standard Back Cane
Back Height	17”-20” Adjustable: 20” or 24” fixed.	20” and 24”
Anti-Tippers	Standard	Standard
Arm Types	Full Adjustable Height, Desk Cantilever	Full Adjustable Height, Desk Cantilever
Wheel Locks	Push-to-Lock (Standard) or Pull-to-Lock, Foot lock	Push-to-Lock (Standard)
Turning Radius	25”	25”
Rear Wheel Sizes	12”-24”	12”-22”
Front riggings	Swing away	Swing away
Product Weight	34.5 lbs. without accessories	50 lbs.
Tilt Range (Tilt in Space Feature)	-5° to 50°	-5° to 50°
Tilt-in-Space	Dual Cable Trigger Mechanism or Foot Pedal Mechanism (Standard)	Dual Cable Trigger Mechanism

[1]Note: *The Low Shear Recline feature is designed to reduce the amount of shear experienced by the user versus the single-pivot recline system incorporated into the predicate device. The Low Shear Recline feature is of similar construction as the single point recline design incorporated into both predicate devices (steel tubing, steel plates, brazed joints, locking gas cylinders and nut/bolt fasteners). The Low Shear Recline feature is operated by two triggers that engage/disengage the locking cylinders via adjustable cables. This is the same operating mechanism as used in the single point pivot design of the predicate devices. Design Verification testing demonstrates that the feature is safe and effective and found to be substantially equivalent to the predicate devices throughout this 510(k) submission.*

Design Comparison – Invacare® Solara® 3G Manual Wheelchair 400 lbs Weight Capacity

Device	Invacare® Solara® 3G Manual Wheelchair	Invacare® Solara® Manual Wheelchairs
510(k) Number	Subject Device Pending Submission	Predicate Device (K984447)
Intended Use	The Invacare® Solara® 3G Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.	Intended to provide mobility to persons limited to a sitting position.
Indications for Use	The Invacare® Solara® 3G Manual Wheelchair and Invacare® Solara® 3G Spree Manual Wheelchair are intended to provide mobility to adults limited to a sitting position.	To provide mobility to adults limited to a sitting position
Design		
Weight Limit	[1]400 lbs. (With Heavy Duty Package)	250 lbs. 300 lbs. (With Heavy Duty Package)
Seat Width	12”-24”	14”-20”
Seat Depth	12”-22”	14”-18”
Back Style	Standard Back Cane [2]Low Sheer Recline (not available on 400 lbs. weight limit wheelchair)	Standard Back Cane
Back Height	17”-20” Adjustable: 20” or 24” fixed.	20” and 24”
Anti-Tippers	Standard	Standard
Arm Types	Full Adjustable Height, Desk Cantilever	Full Adjustable Height, Desk Cantilever
Wheel Locks	Push-to-Lock (Standard) or Pull-to-Lock, Foot lock	Push-to-Lock (Standard)
Turning Radius	25”	25”
Rear Wheel Sizes	12”-24”	12”-22”
Front riggings	Swing away	Swing away
Product Weight	34.5 lbs. without accessories	50 lbs.
Tilt Range (Tilt in Space Feature)	-5° to 50°	-5° to 50°
Tilt-in-Space	Dual Cable Trigger Mechanism or Foot Pedal Mechanism (Standard)	Dual Cable Trigger Mechanism

[1]Note: *Invacare® Solara® 3G Manual Wheelchair 400 lbs weight capacity components and accessories are substantially equivalent to the predicate device identified throughout this submission based on the technological characteristics which includes materials, design, operational principles, and mechanical properties per 21 CFR 807.100(b)(2)(ii)(A). The basic operational principle for the predicate device as well as the subject device is to provide mobility to persons limited to a sitting position. Design Verification testing according to ANSI/RESNA demonstrates that the subject device components and accessories are substantially equivalent to the predicate device regarding static stability, effectiveness of brakes, dimensions, mass and maneuvering space, measurement of seating and wheel dimensions, static impact and fatigue strength, coefficient of friction, information disclosures, documentation and labeling. The subject device’s risk profile remains unchanged and the higher weight capacity do not raise different questions of safety and effectiveness.*

[2]Note: *The Low Shear Recline feature is designed to reduce the amount of shear experienced by the user versus the single-pivot recline system incorporated into the predicate device. The Low Shear Recline feature is of similar construction as the single point recline design incorporated into both predicate devices (steel tubing, steel plates, brazed joints, locking gas cylinders and nut/bolt fasteners). The Low Shear Recline feature is operated by two triggers that engage/disengage the locking cylinders via adjustable cables. This is the same operating mechanism as used in the single point pivot design of the predicate devices. Design Verification testing demonstrates that the feature is safe and effective and found to be substantially equivalent to the predicate devices throughout this 510(k) submission.*

Design Comparison – Invacare® Solara® 3G Spree Manual Wheelchair with 200 lbs Weight Capacity

Device	Invacare® Solara® 3G Spree Manual Wheelchair	Invacare® Solara® Jr. Manual Wheelchairs
510(k) Number	Subject Device Pending Submission	Predicate Device (K012370)
Intended Use	The Invacare® Solara® 3G Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.	To provide mobility to adults limited to a sitting position.
Indications for Use	The Invacare® Solara® 3G Manual Wheelchair and Invacare® Solara® 3G Spree Manual Wheelchair are intended to provide mobility to adults limited to a sitting position.	Persons who may be restricted to a sitting position.
Design		
Weight Limit	[1]200 lbs.	150 lbs.
Seat Width	12”-18”	10”-16”
Seat Depth	12”-19”	12”-18”
Back Style	Standard Back Cane [2]Low Sheer Recline	Standard Back Cane Recliner and Adjustable Angle
Back Height	17”-20” Adjustable 20” and 24” [3]Fixed	20” or 24” Adjustable
Arm Types	Full Adjustable Height, Desk Cantilever	Full Adjustable Height, Desk Cantilever
Rear Wheel Sizes	12”-24”	12”-22”
Front Riggings	Swing away	Swing away
Product Weight	32 lbs. without accessories	27.5 lbs.
Tilt Range (Tilt in Space Feature)	-5° to 50°	-5° to 50°

[1]Note: *Invacare® Solara® 3G Manual Wheelchair 200 lbs weight capacity components and accessories are substantially equivalent to the predicate device identified throughout this submission based on the technological characteristics which includes materials, design, operational principles, and mechanical properties per CFR 807.100(b)(2)(ii)(A). The basic operational principle for the predicate devices as well as the subject devices is to provide mobility to persons limited to a sitting position. Design Verification testing according to ANSI/RESNA demonstrates that the subject device components and accessories are substantially equivalent to the predicate device regarding static stability, effectiveness of brakes, dimensions, mass and maneuvering space, measurement of seating and wheel dimensions, static impact and fatigue strength, coefficient of friction, information disclosures, documentation and labeling. The subject device’s risk profile remains unchanged and the higher weight capacity do not raise different questions of safety and effectiveness.*

[2]Note: *The Low Shear Recline feature is designed to reduce the amount of shear experienced by the user versus the single-pivot recline system incorporated into the predicate device. The Low Shear Recline feature is of similar construction as the single point recline design incorporated into both predicate devices (steel tubing, steel plates, brazed joints, locking gas cylinders and nut/bolt fasteners). The Low Shear Recline feature is operated by two triggers that engage/disengage the locking cylinders via adjustable cables. This is the same operating mechanism as used in the single point pivot design of the predicate devices. Design Verification testing demonstrates that the feature is safe and effective and found to be substantially equivalent to the predicate devices throughout these 510(k) submissions.*

[3]Note: *The subject device fixed back height is similar to the predicate device adjustable back height because the fixed back height was the worst-case scenario used for the testing. The Design Verification testing demonstrated the subject device fixed back height met the requirements acceptance criteria and do not raise different questions of safety and effectiveness. The only difference between the adjustable back height and the fixed back height is that the adjustable back height has the ability to increase the height of the back cane.*

PERFORMANCE DATA

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 device meets the performance requirements and is substantially equivalent to the predicate devices identified throughout this submission.

The following testing was performed:

- ANSI/RESNA WC-1:2009 Section 1: Determination of Static Stability
- ANSI/RESNA WC-1:2009 Section 3: Determination of Effectiveness of Brakes
- ANSI/RESNA WC-1:2009 Section 5: Determination of Dimensions, Mass and Maneuvering Space
- 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-1 :2009 Section 15: Requirements for Information Disclosure, Documentation and Labeling
- ANSI/RESNA WC-1:2009 Section 13: Determination of Coefficient of Friction of Test Surfaces
- ANSI/RESNA WC-1:2009 Section 11: Test Dummies
- CAL 117:2013, Section 1: Flammability Test
- ISO 8191-1:1987 & 8191-2:1988: Flammability Testing

Design Verification Testing demonstrated that the subject Invacare® Solara® 3G Manual Wheelchair with weight capacities of 300 and 400 lbs. and Invacare® Solara® 3G Spree Manual Wheelchair with capacity of 200 lbs. are substantially equivalent to the marketed predicate devices.

Biocompatibility Testing

The biocompatibility evaluation for the subject device was 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

Risk Management

Risk Management has been conducted in accordance with *ISO 14971:2012 - Medical Devices - Application of Risk Management to Medical Devices*" for the subject Invacare® Solara® 3G Manual Wheelchair with weight capacities of 300 and 400 lbs. and Invacare® Solara® 3G Spree Manual Wheelchair with capacity of 200 lbs. The Category Hazard Analysis (CHA) provides guidance on the principal factors to consider in conducting a risk-based assessment to determine the Device Hazard Analysis (DHA) of the subject device's risk profile. The risk assessment Device Hazard Analysis (DHA)involves describing the relationships between a hazard (a potential source of harm) and the ultimate consequences in terms of physical injury or damage. Based on the risk-based assessment Device Hazard Analysis (DHA) performed, the subject device's risk profile remained unchanged and there is no significant impact on the safety or effectiveness of the subject 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 similar technological characteristics as the predicate devices. The performance testing, device comparison, and dimensional analysis demonstrates that the subject device components are substantially equivalent to the predicate devices regarding static stability, effectiveness of brakes, dimensions, mass and maneuvering space, measurement of seating and wheel dimensions, static impact and fatigue strength, coefficient of friction, information disclosures, documentation and labeling. 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.