



Food and Drug Administration
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April 17, 2017

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

Re: K162621

Trade/Device Name: Invacare Tracer SX5 Manual Wheelchair, Invacare Tracer SX5
Recline Manual Wheelchair, Invacare Tracer IV Heavy Duty/Extra
Wide Manual Wheelchair

Regulation Number: 21 CFR 890.3850

Regulation Name: Mechanical Wheelchair

Regulatory Class: Class I

Product Code: IOR

Dated: October 5, 2016

Received: October 6, 2016

Dear Elijah Wreh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); 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 and Part 809), 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

Indications for Use

510(k) Number (if known)

K162621

Device Name

Invacare Tracer SX5 Manual Wheelchair, Invacare Tracer SX5 Recliner Manual Wheelchair, Invacare Tracer IV Heavy Duty/extra Wide Manual Wheelchair

Indications for Use (Describe)

The Invacare® Tracer Manual Wheelchair, Invacare® Tracer® SX5 Manual Wheelchair, Invacare Tracer SX5 Recliner Manual Wheelchair, and Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair are intended to provide mobility 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

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Date Prepared: April 17, 2017

DEVICE
Name of Devices: Invacare Tracer SX5 Manual Wheelchair
Invacare Tracer SX5 Recline Manual Wheelchair
Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair

Common or Usual Name: Wheelchair, Mechanical
Classification Name: Mechanical Wheelchair 21 CFR §890.3850

Regulatory Class: I

Product Code: IOR: Wheelchair, Mechanical

Regulation Description: Mechanical Wheelchair

PREDICATE DEVICE: Tracer Series Mechanical Wheelchairs (K935398)

REFERENCE DEVICE: Ride Lite 9000 Series Wheelchair (K881951)

DEVICE DESCRIPTION

The Invacare® Tracer® SX5 Manual Wheelchair is intended to provide mobility to persons who may be restricted to a sitting position. The manual wheelchair is intended for ongoing daily use. The models offer a wide range of customization which allows for a better fit for the end user resulting in comfort, lightweight, easier propelling, transferring, and smooth ride. The manual wheelchair is intended for indoor and outdoor use on firm surfaces free of climbing obstacles.

The Invacare® Tracer® SX5 Recliner Manual Wheelchair is a Tracer SX5 model with the addition of a recline feature. This recliner model incorporates a mechanism that allows the backrest to recline in angles from 90° to 180°. Both models of the chair have a weight capacity of 250 to 300 lbs. depending on the seat width. Both models also come with an anti-tipper device to ensure the chair remains stable while in use.

The Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair has the same intended use as the Invacare® Tracer® SX5 Manual Wheelchair. However, the Tracer IV does not come with a recliner model and has a higher weight capacity of 350 lbs. or 450lbs. depending on the configuration. Both models of Tracer IV chairs come with a push-to-lock or pull-to-lock feature to engage and disengage the wheel locks. Both models also come with anti-tippers that allow clearance of 1.5 to 2 inches. There is no prior submission for the subject devices.

The associated model and accessories include:

- Invacare Tracer SX5 Manual Wheelchair
 - Seat Width 14” to 18” 250 lbs. (114 Kg)
 - Seat width 20” to 22” 300 lbs. (136 Kg)
- Invacare Tracer SX5 Recline Manual Wheelchair
 - Seat Width 14” to 18” 250 lbs. (114 Kg)
 - Seat width 20” to 22” 300 lbs. (136 Kg)
- Invacare Tracer IV & Heavy Duty Manual Wheelchair
 - Weight capacity at 350 lbs. and 450 lbs.
- Tipper aid
- Cane holder
- Anti-theft device
- Non-folding device
- O₂ holder
- Wheel lock extension
- IV rod telescopic fixed back

INDICATIONS FOR USE

The Invacare® Tracer Manual Wheelchair, Invacare® Tracer® SX5 Manual Wheelchair, Invacare Tracer SX5 Recliner Manual Wheelchair, and Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair are intended to provide mobility to persons limited to a sitting position.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE and REFERENCE DEVICES

The device comparison showed that the subject devices are substantially equivalent in intended use, design, materials, and operational principles to the previously cleared Tracer Series Mechanical Wheelchairs (K935398) to provide mobility to persons limited to a sitting position.

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 major frame components for the subject Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair and the previously cleared Tracer Series Manual Wheelchairs (K935398) are the same. The data generated from the subject Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair test report supports a finding of substantial equivalence in regards to 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® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair and the previously cleared Tracer Series Manual Wheelchairs (K935398) do not raise no new issues of safety or effectiveness.

In conclusion, 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 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.

Design Characteristics Comparison – Invacare® Tracer® SX5 Manual Wheelchair

Device	Invacare® Tracer® SX5 Manual Wheelchair	Tracer Series Manual Wheelchairs
510(k) Number	Subject Devices Pending Submission (K162621)	Predicate Device (K935398)
Intended Use	The Invacare® Tracer® Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.	To provide mobility to persons who may be restricted to a sitting position.
Indications for Use	The Invacare® Tracer® SX5 Manual Wheelchair and Invacare® Tracer® SX5 Recliner Manual Wheelchair are intended to provide mobility to persons limited to a sitting position.	Persons who may be restricted to a sitting position.
Design	Tracer SX5 (Subject Device)	Tracer Series Manual Wheelchairs (K935398)
	250 lbs. 300 lbs.	250 lbs.
Weight Limit Seat Width 14" to 18" Seat Width 20" to 22"	X-design	X-design
Cross-brace Configuration	14", 16", 18", 20" or 22 "	16.5 ", 18 "
Seat Width	14" to 18" with the weight limitation is 250 lbs. 20" to 22" with the weight limitation is 300 lbs.	14" to 18"
Seat Depth	16" to 18"	13", 14", 15", 16", 17", 18", 19", 20", 21" or 22"
Back Style	Fixed	Fixed
Arm Types	Fixed or adjustable height; desk or full length; removable	Permanent and/or Removable
Anti-Tippers	Optional	Optional
Wheel Locks	Push-to-lock and pull-to-lock	Push to lock
Rear Wheel Sizes	20 ", 22", 24 "	20 ", 22", 24 " composite
Caster Sizes	6 " – 8"	6 " – 8"
Front riggings	Swing away	Swing away

Design Characteristics Comparison – Invacare Tracer SX5 Recliner Manual Wheelchair

Device	Invacare Tracer SX5 Recliner Manual Wheelchair	Ride Lite 9000 Series Wheelchair
510(k) Number	Subject Device (K162621)	Reference Device (K881951)
Intended Use	The Invacare® Tracer Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.	The Ride Lite 9000 Series Wheelchair is intended to provide mobility to persons limited to a sitting position.
Indications for Use	The Invacare® Tracer® SX5 Manual Wheelchair and Invacare® Tracer® SX5 Recliner Manual Wheelchair are intended to provide mobility to persons limited to a sitting position	The Ride Lite 9000 Series Wheelchair is indicated to provide mobility to person ages 12 and up (adolescents and adults) with a weight capacity of 350 lb. depending on the seat width.
Design		
Weight Limit	250 lbs. 300 lbs.	350 lb.
Seat Width	16" and 18"	14" and 18 "
Recline Feature	Reclining	Reclining
Cross-brace Configuration	X-design	X-design
Seat Depth	16" and 18"	16", 17" and 18"
Back Style	Reclining (5° – 78° vertical measurement)	Reclining (5° – 78° vertical measurement)
Arm Types	Fixed or adjustable height; desk or full length; removable	Fixed or adjustable height; desk or full length; removable
Anti-Tippers	Required	Required
Wheel Locks	Push-to-lock and pull-to-lock	Push-to-lock and pull-to-lock
Rear Wheel Sizes	20 ", 22", 24"	20 ", 22", 24"
Caster Sizes	6 " – 8"	6 " – 8"
Front riggings	Swing away	Swing away

Note: The reference device is used for the recline feature and technical characteristics comparison.

Design Characteristics Comparison – Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair

Device	Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair	Tracer Series Manual Wheelchairs
510(k) Number	Subject Device Pending Submission (K162621)	Primary Predicate Device (K935398)
Intended Use	The Invacare® Tracer® Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.	To provide mobility to persons who may be restricted to a sitting position.
Indications for Use	The Invacare® Tracer® IV Manual Wheelchair and Invacare® Tracer® IV Heavy Duty/Extra Wide Manual Wheelchair are intended to provide mobility to persons limited to a sitting position.	Persons who may be restricted to a sitting position.
Design		
Weight Limit	350lbs. 450 lbs.	250 lbs.
Cross-brace Configuration	X-design	X-design
Seat Width	18", 20", 22" or 24"	16.5", 18"
Seat Depth	18" and 20"	16", 16"
Back Style	Fixed	Fixed
Arm Types	Fixed or adjustable height; desk or full length; removable	Permanent and/or Removable
Anti-Tippers	Optional	Optional
Wheel Locks	Push to Lock (Adult), Pull to Lock (Hemi)	Push to lock
Rear Wheel Sizes	24" Composite; 24" pneumatic flat free insert	20", 22", 24" composite
Caster Sizes	8 x 1 1/4" Urethane 8 x 1 3/4" Semi Pneumatic	6" – 8" *
Front riggings	Swing away	Swing away

PERFORMANCE DATA

Non-Clinical Test

Non-clinical laboratory testing was performed on the subject Invacare® Tracer Manual Wheelchairs to determine substantial equivalence. The following testing was performed:

- ANSI / RESNA WC/Volume 1 – 2009, Section 1: Determination of Static Stability
- ANSI / RESNA WC/Volume 1 – 2009, Section 3: Determination of Effectiveness of Brakes
- ANSI / RESNA WC/Volume 1 - 2009, Section 5: Determination of Dimensions, Mass and Maneuvering Space
- ANSI / RESNA WC/Volume 1 - 2009, Section 7: Measurement of Seating and Wheel Dimensions
- ANSI / RESNA WC/Volume 1 - 2009, Section 8: Static, Impact and Fatigue Strengths Tests
- RESNA WC-1:2009 Section 11: Test Dummies
- RESNA WC-1:2009 Section 13: Determination of Coefficient of Friction of Test Surfaces
- ANSI / RESNA WC/Volume 1 – 2009, Section 15: Requirements for Information Disclosure, Documentation and Labeling
- CAL117:2013, Section 1: Flammability Testing
- ISO 8191-1:1987 & 8191-2:1988: Flammability Testing

Verification Testing demonstrated that the subject Invacare® Tracer® SX5 Manual and Invacare® Tracer IV® Heavy Duty/Extra Wide Manual are substantially equivalent to the marketed predicate and reference devices.

Biocompatibility Testing

The biocompatibility evaluation for the subject Invacare® Tracer® SX5 Manual and Invacare® Tracer IV® Heavy Duty/Extra Wide Manual 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 devices have the same intended use and similar technological characteristics as the predicate and reference devices. Design Verification Testing support the safety and performance of the subject devices and demonstrate that the subject devices should perform as intended in the specified use conditions. Therefore, the subject Invacare Tracer SX5 Manual Wheelchair, Invacare Tracer SX5 Recline Manual Wheelchair, and Invacare® Tracer IV® Heavy Duty/Extra Wide Manual Wheelchair are substantially equivalent to the predicate and reference devices identified throughout this submission.