



January 12, 2026

Empower Ride LLC
Peter Anaradian
Quality Control Management Manager
18874 Patrick Ave Elkhorn
Elkhorn, Nebraska 68022

Re: K251886
Trade/Device Name: EmpowerRide NAVIGATOR
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR, LBE
Dated: December 11, 2025
Received: December 15, 2025

Dear Peter Anaradian:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Digitally signed by
MARY S. KESZLER-S
Date: 2026.01.12
09:47:31 -05'00'

for Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251886

?

Please provide the device trade name(s).

?

EmpowerRide NAVIGATOR

Please provide your Indications for Use below.

?

The EmpowerRide NAVIGATOR is a manual wheelchair; it is intended to provide mobility to children with disabilities who are partially or permanently non-ambulatory and limited to a sitting position.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?



EmpowerRide LLC

EmpowerRide NAVIGATOR: Manual Wheelchair-Foldable Adaptive Mobility

Base with Seating

18874 Patrick Ave Elkhorn, NE 68022

Model: Navigator

510(k) Summary

Revised January 09, 2026

A. GENERAL INFORMATION

Submitter Name	EmpowerRide LLC
Address	18874 Patrick Ave Elkhorn
State and Zip Code	Nebraska (NE), 68022
Phone	+1 424-219 -6620
Contact Person	Peter Anaradian /Susan Gopaul, Quality Control Management Manager
Serial Number	98337452
Date Prepared	March 11,2025

B. DEVICE

Device Trade Name	EmpowerRide NAVIGATOR
Common/Generic Name	Manual Wheelchair-Foldable Adaptive Mobility Base with Seating
510K Number	K251886
Product Code	IOR, LBE
Device Classification	Class1
Regulatory Number	890.3850

C. IDENTIFICATION OF LEGALLY MARKETED DEVICES

Manufacturer Name	Convoid Products LLC.
Product Name	Convoid Trekker
Model	TR12 and TR14
510K Number	K140416
Product Code	IOR, LBE
Device Classification	Class1
Regulatory Number	890.3850



Manufacturer Name	Convaid Products LLC.
Product Name	Convaid Flyer
Model	FL12, FL13, FL14, FL15 and FL16
510K Number	K171017
Product Code	IOR, LBE
Device Classification	Class1
Regulatory Number	890.3850

Manufacturer Name	Ki Mobility LLC.
Product Name	R82 Kudu
510K Number	K151492
Product Code	IOR, LBE
Device Classification	Class1
Regulatory Number	890.3850



D. DESCRIPTION OF DEVICE

The EmpowerRide NAVIGATOR is a manual pediatric wheelchair intended to provide mobility to children with disabilities who are partially or permanently non-ambulatory and limited to a seated position.

It is designed for caregiver propulsion and is suitable for everyday use in indoor and outdoor environments with flat, firm terrain. The device includes modular adaptive seating and postural supports to meet the therapeutic and mobility needs of pediatric users with neuromuscular, developmental, or orthopedic conditions.

The NAVIGATOR may be used under the supervision of a healthcare provider or selected independently by caregivers for non-complex pediatric mobility needs. The device has been tested and meets the applicable performance and safety requirements of RESNA WC-1:2019 and ISO 7176 standards for manual wheelchairs.

E. INTENDED USE

The EmpowerRide NAVIGATOR is a lightweight, rigid, high-strength aluminium and steel mobility base with a modular, removable adaptive seating system, designed for daily indoor and outdoor use on flat, firm terrain. The device is intended to provide mobility assistance for individuals with physical and/or developmental disabilities that impair independent ambulation, including but not limited to neuromuscular conditions such as cerebral palsy or for individuals with mobility impairments who are non-ambulatory or have limited ability to walk or sit unassisted, including children with developmental or neurological conditions.

As with all caregiver-propelled wheelchair devices, the end user of the EmpowerRide NAVIGATOR is determined by clinical need, body dimensions, and mass. The intended use population is children between the ages of 2–12 years. The NAVIGATOR is prescribed or recommended by a licensed healthcare professional. Warnings and cautions are clearly displayed throughout the Instructions for Use to guide caregivers and ensure safe operation for over the counter use.

A comprehensive risk analysis has been performed to evaluate use by pediatric and other potentially vulnerable populations. Safety-related design features and product labelling have been implemented to mitigate potential risks. The EmpowerRide NAVIGATOR is not intended for use as a motor vehicle seat and has not been tested to WC4:2012 or WC19 standards. It is not equipped with transit tie-downs or occupant restraint systems for vehicular transport.

F. INDICATIONS FOR USE

The EmpowerRide NAVIGATOR is a manual wheelchair; it is intended to provide mobility to children with disabilities who are partially or permanently non-ambulatory and limited to a sitting position.

G. TECHNOLOGICAL CHARACTERISTICS SUMMARY

The EmpowerRide NAVIGATOR is a manual, attendant-propelled pediatric wheelchair constructed from high-strength tubular aluminum. It features a rigid, shock-absorbing foldable base, and a removable modular seating system. The seating insert is fixed-angle and allows for postural positioning or full supine lying when removed. The frame includes adjustable push handles for caregiver comfort. All materials and structural elements meet applicable RESNA WC1 and ISO 7176 standards.



H. COMPARISON OF DEVICE CHARACTERISTICS TO PREDICATES

The EmpowerRide NAVIGATOR is substantially equivalent in design, intended use, materials, and operational characteristics to the predicate devices, the Convaid Trekker (K140416), the Convaid Flyer (K171017) and R82 Kudu(K151492). These are manual, attendant-propelled pediatric wheelchairs intended for users who are partially or permanently non-ambulatory and limited to a sitting position. Each device is intended for indoor and outdoor use on flat, firm terrain.

Although the subject devices use a different carriage design, the transfer activities required for the device were shown not to affect safety or effectiveness when compared to the predicate devices. Testing performed in accordance with ISO 7176 standards confirmed that the device maintains equivalent stability and structural performance during transfers. A usability review following various human-factors principles demonstrated that users perform transfers using the same basic steps physical effort (these are included in the User Instructions Manual) and as with the predicate devices, with only minor differences in hand placement. Therefore, the modified carriage design does not introduce new concerns and does not impact the device's substantial equivalence in safety and effectiveness.

Like the predicates, the EmpowerRide NAVIGATOR is primarily used with children who require postural support and caregiver-propelled mobility. Although the Trekker and other predicates are not age-restricted, their typical user population includes children with disabilities. The NAVIGATOR similarly supports pediatric users with conditions such as cerebral palsy or autism spectrum disorder, and accommodates variability in body size and support needs (Age Range 2-12 Years).The NAVIGATOR features a rigid aluminum base frame and a removable modular seating system that facilitates postural positioning and mobility support. The predicates provide reversible seating (forward- and rear-facing). Although the NAVIGATOR does not include a reversible seating mechanism, its dual push handle design allows the caregiver to maintain direct visual and physical interaction with the child, achieving the same clinical and practical benefits as the predicates' rear-facing seat configuration.

The NAVIGATOR incorporates a folding frame for ease of transport and compact storage. Although the predicates include a tilt-in-space and mechanical recline function, the EmpowerRide NAVIGATOR achieves functional versatility through modular seat inserts. The NAVIGATOR's seat module can be removed and replaced with a flat-lying platform when clinically indicated. This feature addresses the same clinical needs as recline and tilt functions, without integrating mechanical adjustment systems.

Although tilt-in-space functionality may facilitate transfers in certain designs, it is not required to ensure safe and effective transfer performance. From a risk-management perspective (ISO 14971), the absence of tilt-in-space does not introduce new hazards. Transfer-related hazards (e.g., instability, unintended motion, user displacement) are adequately controlled through a fixed, non-articulating seating orientation that provides a predictable support surface during transfer, open access frame geometry compatible with standard caregiver-assisted transfer techniques, and a stable base designed to resist tipping and unintended displacement under reasonably foreseeable transfer loads and conditions of use.

Elimination of the tilt-in-space mechanism further reduces mechanical complexity and removes hazards associated with articulated components, including unintended actuation, and mechanical failure during transfer. The device is designed to maintain static stability during transfer activities consistent with its intended use and comparable legally marketed devices without tilt-in-space functionality. Transfer procedures, warnings, and limitations are clearly defined in the Instructions for Use and serve as additional risk controls. Based on the implemented design controls and instructions, the residual risk associated with transfer activities is acceptable and comparable to that of the predicate devices; therefore, the absence of a



tilt-in-space feature does not raise new questions of safety or effectiveness.

The NAVIGATOR and predicates were tested under the same applicable sections of RESNA WC1 and ISO7176 standards, including ISO 7176-1:2014 (Static Stability), ISO 7176-3:2012 (Brake Effectiveness), ISO 7176-5:2008 (Dimensions, Mass, and Maneuvering Space), ISO 7176-7:1998 (Seating and Wheel Measurements), ISO 7176-8:2014 (Static, Impact, and Fatigue Strengths), resistance of arm supports and push handles to downward and upward forces, manual wheelchair drum test (200,000 revolutions), drop test (6,666 cycles), tipping levers, and brake performance and fatigue.

Surface properties and safety testing included ISO 7176-13:1989 (Coefficient of Friction of Test Surfaces) and RESNA WC-1:2019 Sections 1 (Static Stability), 3 (Effectiveness of Brakes), 5 (Dimensions and Maneuverability), 7 (Seat and Wheel Dimensions), 8 (Static, Impact, and Fatigue Strength), 13 (Coefficient of Friction), 15 (Labeling, Documentation, and Information Disclosure), and 16 (Resistance to Ignition - Upholstery materials).

Test dummies used included 75 kg for RESNA brake testing and 150 kg for ISO 7176-8 structural load testing. All tests were passed with no evidence of material failure or performance degradation, confirming that the EmpowerRide NAVIGATOR does not raise new questions of safety or effectiveness when. The minor technological differences such as seat orientation and recline method do not affect the intended use or fundamental scientific technology. Based on device design, materials, performance, and testing, the EmpowerRide NAVIGATOR is substantially equivalent to the Predicates.

The Comparison Table between EmpowerRide and its predicates is given below:

Device Feature	EmpowerRide NAVIGATOR	Convaid Trekker TR12 and TR14 (Primary)	Convaid Flyer FL12, FL13, FL14, FL15 and FL16 (Secondary)	R82 Kudu (Tertiary)	Comparison to Predicate
510(k) Number	K251886	K140416	K171017	K151492	FDA assigns this unique number to every device.
Regulation Number	21 CFR 890.3850	21 CFR 890.3850	21 CFR 890.3850	21 CFR 890.3850	Identical. All devices fall under the same regulation number.
Product Code	IOR, LBE	IOR, LBE	IOR, LBE	IOR, LBE	Identical. All devices share the same product codes.
Intended Use	The EmpowerRide NAVIGATOR is a lightweight, rigid high-strength aluminum and steel wheelchair base with a removable adaptive seating system for indoor and outdoor use on flat, firm terrain. It is intended for pediatric users with mobility impairments resulting from neuromuscular, orthopedic, or neurodevelopmental conditions, such as cerebral palsy, hypotonia, genetic syndromes, or developmental disorders	The Convaid Trekker is a lightweight, rigid high-strength aluminum and steel wheelchair base with a removable seating system designed for children with mobility limitations caused by neuromuscular, orthopedic, or neurodevelopmental conditions. These may include diagnoses such as cerebral palsy, spina bifida, muscular dystrophy, or global developmental delay that impair gait, posture, or independent sitting. The device supports	A manual, pediatric tilt-in-space wheelchair with removable seating, designed for indoor/outdoor use on firm, flat terrain.	Designed to provide mobility to children and adults with disabilities.	The Intended Use is substantially similar to the predicate devices. It is nearly identical to the secondary predicate (Flyer) in its description as a lightweight, rigid wheelchair with an adaptive seating system for pediatric users with neuromuscular conditions.



	that affect ambulation or postural stability. Risk analysis has been conducted to ensure safe use by children with disabilities.	safe everyday mobility across various pediatric user sizes.			
Indications for Use	The EmpowerRide NAVIGATOR is a manual wheelchair; it is intended to provide mobility to children with disabilities who are partially or permanently non-ambulatory and limited to a sitting position.	The Convaid Trekker models are manual wheelchairs; their intended use is to provide mobility to persons with disabilities who are partially or permanently non-ambulatory and limited to a sitting position. The end user is not determined by age but by body dimensions and mass, and may include both children and adults. In addition, the Trekker Transit models TR12T and TR14T comply with the requirements of RESNA WC4:2012 Section 19 for wheelchairs u	Provides mobility support for children with disabilities who are partially or permanently non-ambulatory and confined to sitting.	Designed for children requiring postural positioning and mobility in a single device.	The Indications for Use are identical to the primary and secondary predicates. All devices are intended to provide mobility for individuals who are partially or permanently non-ambulatory and limited to a sitting position.
Device Type	Manual Pediatric Wheelchair	Manual Pediatric Wheelchair	Manual Pediatric Wheelchair	Manual Pediatric Wheelchair	Same as all predicate devices.
Patient Population	Pediatric	Pediatric -young adolescents	Pediatric -young adolescents	Pediatric - young adolescents	Identical to predicate devices. All devices, including the subject device (NAVIGATOR), are indicated for use in pediatric populations.
Crash Tested	No	Yes (Transit models only)	Yes (Transit models only)	Yes	Different. The NAVIGATOR is not designed or tested for use as a seat in a motor vehicle, unlike the predicate devices.
Transit Approved	No (Not WC19)	Yes (Transit models only)	Yes (Transit models only)	Yes (WC19)	Different. The subject device is not intended for transit use (per RESNA WC19), which is a key difference in the scope of use but does not raise new safety concerns for its intended environment.
Testing Standard	ISO 7176 / RESNA WC-1:2019	ISO 7176 / RESNA	ISO 7176 / RESNA	ISO 7176 / RESNA	Same as predicate devices. All devices are tested to the recognized



					ISO 7176 and RESNA standards for manual wheelchairs.
Frame Material	6061 Powder-Coated Aluminum	6061 Powder-Coated Aluminum	6061 Powder-Coated Aluminum	Aluminum Frame	Same as predicate devices. All utilize aluminum for the frame construction.
Armrest Option	Yes	Optional	Yes	Yes	Similar to predicate devices. All devices offer armrests as a standard or optional feature.
Wheel Locks	Foot-actuated	Foot-actuated	Foot-actuated	Manual	Identical to the primary and secondary predicates (Foot-actuated). All devices use functionally equivalent manual wheel locks.
Frame Coating	Powder-coated	Powder-coated	Powder-coated	Anodized or painted	Similar to predicate devices. All use standard industry methods for frame finishing.
Camber	No	N/A	N/A	Yes	Same as primary and secondary predicates. The absence of camber is appropriate for this type of wheelchair and does not impact safety or effectiveness.
Front Caster Diameter	8.5"	6" or 7.5"	6" or 7.5"	175 mm (~6.9")	Similar to predicate devices. The caster diameter falls within the typical range for such devices and does not affect safety or effectiveness.
Rear Wheel Diameter	14"	11.5" or 16"	11.5" or 16"	11.8"	Similar to predicate devices. The 14" rear wheel diameter is within the range of sizes offered by the predicates (11.5" - 16").
Propulsion Type	Attendant	Attendant	Attendant	Attendant or Self	Same as the primary and



					secondary predicates. The device is attendant-propelled, a feature shared with all predicates.
Seat Width	22"	12"	12" to 16"	15"	Different. The NAVIGATOR offers a larger seat width to accommodate a larger pediatric patient. This dimensional difference does not affect the device's fundamental safety or intended use.
Seat Depth	13.98"	6" to 12"	15.5" to 25.5"	13.5" to 27.5"	Similar to predicate devices. The seat depth is comparable to the ranges offered by the secondary and tertiary predicates.
Seat to Back Height	15.67"	15" to 21"	17" to 23"	17" to 24.5"	Similar to predicate devices. The seat-to-back height falls within the adjustment range of the primary predicate.
Seat to Footrest	13" standard (14" to 16" with accessory seat)	6" to 14"	5.8" to 11"	10" to 17.5"	Similar to predicate devices. The seat-to-footrest adjustment range is within the overall range provided by the predicates.
Footplate Adjustability	No	+/-15°	+/-15°	Yes	Different. The subject device has a fixed-angle footplate, unlike the predicates. This design simplification does not impact fundamental safety or effectiveness.
Seat to Floor Height	22.05"	16-25"	15"	18.75"	Similar to the primary predicate. The



					seat-to-floor height is within the range of the Trekker model and is consistent with the overall larger sizing of the device.
Seat to Back Recline	Not integrated. The main seat does not feature an adjustable recline. However, when the optional postural support seat is removed, the user can lie flat in the base frame, providing functional recline equivalent to a supine position. This configuration supports passive positioning rather than dynamic recline adjustment.	80° to 170°	80° to 170°	80° to 180°	Different mechanism, similar function. While predicates have integrated recline, the NAVIGATOR achieves postural recline via an accessory. Both support a supine position.
Tilt-in-Space	No	-5° to 45°	-5° to 40°	-3° to 45°	Different. The absence of a tilt-in-space feature does not introduce new transfer-related hazards, as transfer safety is adequately controlled through a fixed, stable seating orientation, open access geometry, and a stable base under reasonably foreseeable transfer conditions. Removal of articulated tilt components reduces mechanical complexity and associated hazards; therefore, residual risk is comparable to predicate devices and does not raise new questions of safety or effectiveness.
Headrest Extension	No	6"	8"	Varies	Different. The subject device does not have a



					headrest extension, unlike all predicates. This represents a more basic design which does not raise new safety issues.
Chair Weight	20 lbs.	32 lbs.	29.2 lbs.	40.3 lbs.	Different. The subject device is substantially lighter than all predicate devices, which may enhance portability and ease of use.
Chair Width	22.25"	24.3"	21" to 25"	27.5"	Similar to predicate devices. The overall width is within the range of the predicate models.
Overall Height	40"	37.5"	40"	37"	Same as predicate devices. The overall height is consistent with the predicate models.
Overall Length	40.5"	42"	25.75"	29"	Similar to the primary predicate. The overall length is comparable to other wheelchairs of this type.
Weight Capacity	165.347 lbs /75 kg	75–110 lbs.	85–170 lbs.	132 lbs.	Similar to the predicate devices. The overall weight capacity is comparable to the predicate models.
Tilt Lock Type	None	Single Mech Lock	Single Mech Lock	Varies	Not applicable. As the device does not have a tilt feature, it does not require a tilt lock.
Removable Seating Module	Yes	Yes	Yes	Yes	Same as all predicate devices.
Rx and OTC	Both	OTC Only	OTC Only	Both	Like Kudu, the device is accessible both by prescription and over-the-counter, whereas Trekker and Flyer are OTC only.



I. NON-CLINICAL TESTING

The EmpowerRide NAVIGATOR pediatric wheelchair has been subjected to a comprehensive suite of non-clinical performance and safety testing to validate its structural integrity, safety, and suitability for pediatric use. All testing was conducted by Intertek Testing Services Shenzhen Ltd. The device was evaluated using the following standards:

Mechanical and Structural Performance Testing (ISO & RESNA WC-1:2019):

- ISO 7176-1:2014 – Static Stability
- ISO 7176-3:2012 – Brake Effectiveness
- ISO 7176-5:2008 – Dimensions, Mass, and Maneuvering Space
- ISO 7176-7:1998 – Seating and Wheel Measurements
- ISO 7176-8:2014 – Static, Impact, and Fatigue Strengths
 - ✓ Arm supports – resistance to downward and upward forces
 - ✓ Push handles – resistance to upward load
 - ✓ Manual wheelchair drum test – completed 200,000 revolutions (dynamic loading)
 - ✓ Drop test – completed 6,666 cycles per RESNA requirements
 - ✓ Tipping levers
 - ✓ Brake performance and fatigue

Surface Properties and Safety Testing:

- ISO 7176-13:1989 – Coefficient of Friction of Test Surfaces
- RESNA WC-1:2019
 - ✓ Section 1 – Static Stability
 - ✓ Section 3 – Effectiveness of Brakes
 - ✓ Section 5 – Dimensions and Maneuverability
 - ✓ Section 7 – Seat and Wheel Dimensions
 - ✓ Section 8 – Static, Impact, and Fatigue Strength
 - ✓ Section 11 - Test Mannequins
 - ✓ Section 13 – Coefficient of Friction
 - ✓ Section 15 – Labeling and Information Disclosure
 - ✓ Section 16 –Upholstery Flammability

Test dummies used:

- 75 kg for RESNA brake testing protocol
- 150 kg for ISO 7176-8 structural and fatigue testing

All performance and durability tests were successfully passed with no evidence of material failure or structural compromise. The EmpowerRide NAVIGATOR meets or exceeds the performance requirements established in the RESNA and ISO standards listed above.



These test methods are consistent with those used in the validation of the predicate devices. As such, the EmpowerRide NAVIGATOR does not raise any new safety or effectiveness concerns and is substantially equivalent to the predicate devices in terms of non-clinical performance.

J. PRESCRIPTION AND OVER THE COUNTER USE:

This device is available for both prescription use and over-the-counter use:

- For prescription use: Use only under the direction of a licensed healthcare professional in accordance with 21 CFR 801.109.
- For over-the-counter use: Caregivers should carefully follow all instructions provided in the User Manual.

K. STORAGE/SHELF LIFE

The EmpowerRide NAVIGATOR pediatric wheelchair is manufactured in standard configurations and packaged for distribution. Storage and shelf-life considerations apply primarily to unused units prior to delivery to the end user.

The unit should be stored in a clean, dry area away from direct sunlight and excessive humidity. Avoid exposure to high heat or moisture to prevent material degradation. If the unit remains unused for an extended period, a full inspection and functional check should be conducted before use. Refer to the maintenance guidelines in the manual for proper servicing intervals.

L. BIOCOMPATIBILITY

The patient-contacting textile is a woven/knitted PET fabric. The patient-contacting fabric used in the NAVIGATOR device is composed of 100% Polyethylene Terephthalate (PET), confirmed through supplier documentation, MSDS, and OEKO-TEX Standard 100 Annex 6 certification. The material has indirect, prolonged skin contact (>24 hours), consistent with FDA's 2023 Biocompatibility Guidance (Attachment G) classification for non-critical, skin-contacting devices. PET is a well-characterized, chemically stable polymer with a long history of safe use in FDA-cleared Class I and II medical devices, supporting its compliance with ISO 10993-1 and 10993-5 principles. Chemical safety is further demonstrated through OEKO-TEX certification and CPSIA testing (Intertek Report No. GZHH00583833), confirming non-detectable levels of lead and phthalates. These data address key toxicological endpoints related to cytotoxicity, irritation and sensitization.

M. SAFETY AND EFFECTIVENESS

The EmpowerRide NAVIGATOR pediatric wheelchair shares similar technology, and intended use with the predicate devices K140416, K171017 and K151492. The NAVIGATOR introduces no new issues of safety or effectiveness. Mechanical performance, durability, and patient-contacting materials meet applicable ISO and RESNA standards, supporting its safe and effective use.



N. CONCLUSION

The EmpowerRide NAVIGATOR pediatric wheelchair is substantially equivalent to the Convaid Trekker (K140416) and similar predicate devices (K171017 and K151492) cleared under 21 CFR 890.3850. The NAVIGATOR matches the intended use, technical characteristics, and performance specifications of the predicate devices. It is intended to provide mobility assistance to pediatric users who are partially or permanently non-ambulatory, consistent with the use described in the predicates.

Testing confirms that the NAVIGATOR meets or exceeds the applicable ISO and RESNA performance standards for mechanical safety, stability, and durability. The device utilizes materials and components that are commonly used in pediatric wheelchairs.

While the EmpowerRide NAVIGATOR incorporates modular enhancements and caregiver-friendly features not found on the predicate devices, these differences do not affect safety or effectiveness. The enhancements support ease of use, adaptability, and caregiver control, without introducing new risks. Accordingly, there are no significant differences in intended use, technological characteristics, or performance that raise new questions of safety or effectiveness. The EmpowerRide NAVIGATOR is therefore substantially equivalent to the legally marketed predicate devices.