June 24, 2022

RoughRider America LLC
Marc Krizack
CEO
2233 California Street
Berkley, California 94703

Re: K200715
Trade/Device Name: RoughRider America™ RoughRider Aurora™ Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: April 4, 2022
Received: April 26, 2022

Dear Marc Krizack:

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/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 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 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,

for Heather Dean, PhD
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

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)*
K200715

Device Name
RoughRider America™ RoughRider Aurora™ Manual Wheelchair

Indications for Use *(Describe)*
The RoughRider America™ RoughRider Aurora™ Manual Wheelchair is indicated to provide mobility to persons restricted to a seated position up to a weight capacity of up to 250 lb / 114 kg.

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

SUBMITTER (per 21 CFR 807.92(a)(1))

RoughRider America LLC
2233 California Street,
Berkeley, CA 94703, USA

Primary Contact Person	Name:	Marc Krizack
	Phone:	510 548-1333
	Email:	marc@rougrideramerica.com
Manufacturing Site	Name:	Merits Healthcare Industries (Suzhou) Co., Ltd. No. 29, Liangfu Road, Taicang City, Jiangsu Province 215411, China
Date summary prepared:		April 04, 2022

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

Name of Device:	RoughRider America™ RoughRider Aurora™ Manual Wheelchair
Common or Usual Name:	Manual Wheelchair
Regulation Description:	Wheelchair, Mechanical
Regulation Number:	21CFR 890.3850
Review Panel:	Physical Medicine
Regulatory Class:	Class I
Product Code:	IOR
510(k) Number:	K200715

PREDICATE DEVICE

Predicate Device Name:	Whirlwind RoughRider Wheelchair
510(k) Number:	K103212

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

The RoughRider America™ RoughRider Aurora™ Manual Wheelchair (Aurora) is a user propelled, manually operated folding wheelchair. The Aurora is designed for everyday use and to help its rider move around easily, safely, and without the restrictions imposed by much of the terrain encounter in daily life. The Aurora is expected to perform well:

- Indoors and outdoors;
- Over smooth, rough, and uneven ground;
- Over soft and hard surfaces;
- Over small obstacles, like door jams; and
- Up, down and across slopes.

The Aurora utilizes primarily aluminum tubing that is bent, fastened, and/or welded to create a frame. The frame is comprised primarily of side frame, X-brace, foot rest, and caster fork sub-assemblies. Upholstery is made from fire-resistance fabric. The rear wheels of the Aurora can be removed making the wheelchair lighter for lifting or carrying.

The side frames have three axle holes that allow the rear wheel position to be adjusted forward and backward. Wheel position affects the rider's forward and backward stability by changing wheel axle position relative to the person's center of gravity. The position of the rear wheel relative to the rider's center of gravity also affects the amount of the rider's weight that is distributed onto the front casters, and allows the rider to maximize maneuverability and control.

The Aurora side frame fenders act as fixed arm rests and enable transferring in and out of the wheelchair. The side frame also includes the backrest tubes and push handles. The backrest tubes can be adjusted up and down to meet basic support requirements of the rider and/or their companion. Wheel locks attach to the side frame and prevent the rear wheels from turning. The locks keep the wheels from moving during transfers or when a stationary position is necessary.

An X-Brace connects the side frames of the wheelchair together, determines the chair width, and allows the frame to fold. With the X-Brace in the unfolded position, the chair performs much like a typical X-Brace folding wheelchair. The Aurora can be easily folded for stowage or storage and fits easily into the cargo carrying areas of most vehicles.

The seat upholstery fastens to the top surface of each X-brace seat tube and provides support for the rider to sit. The angled, sling-style seat and tension-adjustable back fabric offers seating suitable for many different riders. The tilted seat helps keep the rider slightly reclined to reduce the chances of tipping forward and out of the chair. The back fabric can be adjusted to increase or reduce back fabric tension. The seat width of the Aurora is determined by the size of the x-

brace and the seat fabric and fixed at the point of fabrication, based on the customer order. The seat can be used with a range of wheelchair and flotation (pressure relief) cushions.

The footrests are not easily removable and support the rider's lower legs or feet. The footrests are independently adjustable up and down to position the rider's legs appropriately. The footrests are hinged and can be folded up to enable easier transfers into and out of the Aurora. When the Aurora is unfolded, and the rider is sitting in the chair, the footrest design can give the rider added protection for their toes from doors or other obstacles.

The casters include the caster wheels (hubs and tires) and a caster fork. The caster is mounted to the front of the side frame using the caster barrel. The casters can turn freely 360°. The casters of the Aurora are positioned approximately five inches further forward than most hospital- or box-style wheelchair designs. This additional distance gives the rider of the Aurora a stable ride, in terms of forward stability.

To prevent unintended changes to the chair configuration and reduce risk to the rider, most adjustment (footrest and backrest height) require access to basic tools.

The maximum weight capacity of the chair is 250 lb (114kg).

The Aurora is based on and substantially equivalent to the established and tested design, of the Whirlwind RoughRider. This design has been refined with input from thousands of wheelchair riders around the world after over 15 years of use. The Aurora is easy to clean and uses a range of standardized components that are easy to maintain and replace.

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

The RoughRider America™ RoughRider Aurora™ Manual Wheelchair is intended to provide mobility to persons restricted to a seated position.

INDICATIONS FOR USE (per FORM FDA 3881)

The RoughRider America™ RoughRider Aurora™ Manual Wheelchair is indicated to provide mobility to persons restricted to a seated position and up to a weight of 250 lb / 114 kg.

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

Specification: Units in millimeters and inches unless specified.	**Subject Device***		**Predicate Device***
	Min	**Max**	
Maximum occupant mass:	114 kg (250 lb)	114 kg (250 lb)	220 lb
Overall length with leg rest (footrest) [1]	1020 (40.25)	1110 (43.7)	Not Publicly Available
Overall width [1]	635 (25), 675 (26.5), 710 (28), 750 (29.5)		
Folded length [1]	1040 (41)	1110 (43.7)	Not Publicly Available
Folded width [1]	410 (16)	410 (16)	Not Publicly Available
Folded height [1]	500 (19.5)	875 (34.5)	Not Publicly Available
Total mass (kg / lb) [1]	18 kg (38.5 lb)	18 kg (38.5 lb)	Not Publicly Available
Mass of the heaviest part (kg/ lb) [1]	N/A	N/A	Not Publicly Available
Static stability downhill [2]	31°	31°	Not Publicly Available
Static stability uphill [2]	9°	21°	Not Publicly Available
Static stability sideways [2]	20°	20°	Not Publicly Available
Seat plane angle [3]	15°	15°	Not Publicly Available
Effective seat depth [3]	395 (15.5), 445 (17.5), 495 (19.5)		
Effective seat width [3]	350 (13.75), 385 (15.25), 425 (16.75), 465 (18.25)		
Seat surface height at front edge [3]	585 (23)	585 (23)	Not Publicly Available
Backrest angle [3]	18.6°	18.6°	Not Publicly Available
Backrest height [3]	250 (9.75), 300 (11.75), 350 (13.75), 400 (15.75)		
Footrest to seat distance [3]	430 (17)	485 (19)	Not Publicly Available
Leg to seat surface angle [3]	87°	87°	Not Publicly Available
Armrest to seat distance [3]	N/A	N/A	Not Publicly Available
Front location of armrest structure [3]	N/A	N/A	Not Publicly Available
Hand rim diameter [3]	475 (18.75)	475 (18.75)	Not Publicly Available
Horizontal location of axle [3]	140 (5.5)	65 (2.5)	Not Publicly Available
Minimum turning radius [1]	N/A	N/A	Not Publicly Available
Wheelbase (Front Axle to Rear Axle)	600 (23.5)	675 (26.5)	Not Publicly Available

[1] Measured in conformance with ISO 7176-5:2008 Wheelchairs — Part 5: Determination of dimensions, mass and manoeuvring space

[2] Measured in conformance with ISO 7176-1:2014 – Wheelchairs – Part 1: Determination of static stability

[3] Measured in conformance with ISO 7176-7:1998 Wheelchairs — Part 7: Measurement of seating and wheel dimensions

KEY SIMILARITIES:

- The RoughRider America™ RoughRider Aurora™ Manual Wheelchair (Aurora) is substantially equivalent to the Whirlwind RoughRider (Whirlwind) in its intended use, design, fabrication processes, and functionality. Both wheelchairs are intended to provide mobility to persons restricted to a sitting position. Both wheelchairs are manual wheelchairs, propelled using push rims, or pushed by a helper using the push handles.
- The overall dimensions of the both wheelchairs when open and closed are equivalent. The minimum and maximum length of the wheelbase are equivalent. Both wheelchairs feature X-Brace-style folding frames, non-removable folding footrests. The footrest of both wheelchairs are fixed laterally and do not swing away, but can be folded up to allow open entrance for the rider's entry and exit from the wheelchair. Both wheelchairs feature a fabric seat sling over an X-Brace style of folding mechanism.
- Both the wheelchairs use solid rubber front caster tires and pneumatic rear wheels.

KEY DIFFERENCES:

- The Aurora frame is manufactured using aluminum. The Whirlwind frame is made from carbon steel. While the materials are different metal alloys, the methods for forming the frame parts and joining them together are similar and well-established processes. Testing to recognized consensus standards has demonstrated the durability of the aluminum frame.
- The Aurora weighs less than the Whirlwind of equivalent size due to the difference in the weight of the frame. The reduction in weight is beneficial to the rider and their helper as the chair requires less energy to propel and lift when compared to the predicate chair.
- The Aurora has fewer rear wheel positions than the Whirlwind. The Aurora offers 3 rear wheel positions, while the Whirlwind offers 5 positions. The reduction in the number of wheel positions simplifies the configuration of the chair by or for the rider, without affecting the safety or effectiveness.
- The Aurora has a weight capacity of 250 lb. The Whirlwind has a weight capacity of 220 lb. The aluminum frame enables the Aurora to safely support greater loads than the Whirlwind. Testing to recognized consensus standards has demonstrated the greater load capacity of the Aurora.
- Minor changes have been made to the seat width and depth ranges of the Aurora based on expectations of the US market.
- The Aurora includes an adjustable back rest to better accommodate people of a range of torso heights. The Whirlwind backrest height is fixed. Testing has demonstrated the durability of the Aurora back rest and push handles.

PERFORMANCE DATA

The following FDA-Recognized Consensus Standards have been used when testing the Aurora. The applicable tests described in these standards were passed.

- ISO 7176-1 Third edition 2014-10-01 - Wheelchairs - Part 1: Determination of static stability
- ISO 7176-3 Third edition 2012-12-15 - Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-5 Second edition 2008-06-01 - Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- 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 7176-11 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 surfaces
- ISO 7176-15 First edition 1996-11-15 - Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- ISO 7176-16 Second edition 2012-12-01 - Wheelchairs - Part 16: Resistance to ignition of postural support devices
- ISO 7176-22 Second edition 2014-09-01 Wheelchairs - Part 22: Set-up procedures

CONCLUSION

The Aurora and the Whirlwind (predicate device) have the same intended use, indications for use, overall design envelope, fabrication methods, and functionality for the wheelchair rider. The major difference is the material used to construct the Aurora frame, resulting in a lighter wheelchair. The Aurora has been tested and meets the performance standards described. The Aurora is substantially equivalent to the predicate device.