May 12, 2022

Zhejiang Innuovo Rehabilitation Devices Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K220740
Trade/Device Name: Power Wheelchair, W5907
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 14, 2022
Received: March 14, 2022

Dear Ivy Wang:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220740

Device Name
Power Wheelchair, W5907

Indications for Use *(Describe)*
The Power Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated 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

I. SUBMITTER

Name: Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

Address: No.196 Industry Road, Hengdian Movie Zone, Dongyang, Zhejiang, China

Name of contact person: Leo Zheng

Telephone: +86 18358936043

Fax: +86-579-89327232

Date prepared: 2022-05-05

II. Device

Device trade name: Power Wheelchair, W5907

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K113463

Power wheelchair, PL00l

SUZHOU KD Medical Appliance Co. Ltd.

IV. Device description

This Power wheelchair is a motor driven, indoor and outdoor transportation vehicle, which a device for assisting action handicapped people and disabled people to move. It is suitable for disabled people with mobility difficulties and elderly people.

The device consists of front wheel, drive wheel, frame, controller, motor, armrest, push-handle, backrest, seat cushion, pedal, battery box and charger.

The device is powered by 2 Li-ion Battery pack (24V 10Ah, 240Wh) with 20 Km (12.5 miles) range, which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet (100-240V, 50/60Hz) when the device is not in use.

The patient can activate the controller handle (joystick) to control the speed and direction of the wheelchair movement. In addition, when the patient releases the joystick, the joystick will return back to the central position and the wheelchair will be automatically stopped soon due to automatic electromagnetic brake system. Once the joystick is activated again move to other position, the wheelchair will be re-energized.

V. Indication for use

The Power Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

VI. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicate device	Discussion/ Conclusion
Manufacturer	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	SUZHOU KD Medical Appliance Co. Ltd.	/
Proprietary name, model	Power Wheelchair, W5907 (Q50 R Carbon)	power wheelchair, PL00l	/
510(k) number	K220740	K113463	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same
Similarities			
Indication for use	The Power Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	They are motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	Same
Intended user	disabled people with mobility difficulties and elderly people	disabled or elderly person limited to a seated position	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same
Function of wheels	Front wheels: driven	two pivoting casters: driven	Same

Attribute	Subject device	Predicate device	Discussion/ Conclusion
	wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	wheels suitable for rotation, acceleration, retrograde two rear drive wheels: driving wheels to control the speed and direction	
Movement control method	By Joystick control	By Joystick control	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake system	Automatic electromagnetic brake system	Intelligent regenerative Electromagnetic brake	Same
Braking distance	≤1.5 m	Forward: 1.5m (59”) at max speed	Same
Battery	li-ion battery pack; rechargeable, 24 VDC 10Ah *2pcs	Li-ion, Rechargeable; 24 VDC 20Ah	Same
Maximum distance of travel on the fully charged battery	20 km	20 km	Same
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Off-board, Automatic Type Input: 110-220 V / 50-60 Hz, Output: 24 Vdc, 2A;	Same
Differences			
Main frame material	Carbon fiber material	aluminum alloy	Different material used for frame, that such difference will not impact the safety and effectiveness of the subject device as the performance tests are conducted according to ISO 7176 series. The carbon fiber material is lighter and easy to carry.
back cushion	Polyester fabric	PU foam covered by nylon fabric cloth	different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the

Attribute	Subject device	Predicate device	Discussion/ Conclusion
			subject device as biocompatibility tests are carried out according to ISO 10993 series.
seat cushion	rubber patch cloth and Oxford fabric	PU foam covered by nylon fabric cloth	different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility tests are carried out according to ISO 10993 series.
Armrest	T700	PU	Different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility tests are carried out according to ISO 10993 series.
Overall Dimension (length*width*height)	923*570*928mm	880*570*890mm	Minor difference on wheelchair dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Stowage Dimension (length*width*height)	370*570*767mm	720*570*400mm	
Front wheel size/type	6.5" x 1.5"/PU Solid tire	6″ x 2″ /PU Solid tire	Minor difference on dimension of driven wheel will not cause different performance.
Rear wheel size/type	8.5″x 1.8″/ PU Solid tire	8" x 2.4"/PU Solid tire	Minor difference on dimension of driving wheel will not cause different performance.
Max speed forward	Up to 6 km/h (1.6 m/s), adjustable	Up to 6 km/h (3.75 mph), variable	minor difference on max. forwarding speed will not

Attribute	Subject device	Predicate device	Discussion/ Conclusion
			cause different performance. lower speed will be more safety.
Max Speed backward	Less than 3 km/h (0.4m/s)	2.4 mph (3.84 km/h)	lower speed on max. backward speed will be more safety.
Max loading weight	136kg (≈300 lbs)	114 kg (251 1bs)	Difference on loading weight will not cause different performance. more loading weight provide more convenient and stable performance for the transportation.
Maximum safe operational incline degree	8 °	9 °	minor difference on safe operational incline degree will not cause new safety and effectiveness concerns are raised as both the static and dynamic stability under specific inclining degree have been evaluated according to standard ISO 7176 series.
Motor	Brushless DC motor; 24VDC; 250W; 2pcs	Brushless DC motor; 24 VDC; 180 W; 2 pcs	minor difference on motor power will not cause different performance. larger power will provide more driving force, no safety and effectiveness concerns raised.
Electronic controller	Brushless dual-drive rocker controller	Brushless dual-drive rocker controller	Similar controller is used, both the control system, including the joystick controller, the electromagnetic brakes and the user interface are similar. The joystick controls the directions

Attribute	Subject device	Predicate device	Discussion/ Conclusion
			and speed of movement, and when the joystick is released, the powered wheelchair will slow down to stop and the brakes will automatically re-engage. The controller also provides the battery status displaying and abnormal condition displaying. Both of the control systems are evaluated according to standard ISO 7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Turning Radius	765 mm	31.5” (800 mm)	The minor difference in the turning radius is caused by different size of wheelchair and may cause a little bit inconvenience when it turns in a narrow space while the minor difference will not raise any new safety and effectiveness concerns.
Maximum obstacle climbing	40 mm	1.2” (30 mm)	Longer distance in the obstacle climbing will not impact the safety and effectiveness of the subject device.

VII. Summary of substantial equivalence discussion

The power wheelchair complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2001, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2008, ISO

7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 7176-16:2012, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2: 2014, ISO 10993-1:2018, ISO10993-5:2009, ISO 10993-10:2010.

The intended uses for both devices are the same. Mainframes of two devices are folded by way of front and rear close, and frame materials all meet the Tensile Strength, Yield Load, and Elongation tests. The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14:2008. Software validation is carried out on both control systems. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3:2012. Maximum obstacle climbing and Maximum safe operational incline are slightly different while such differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns as well as both meet the requirements of the ISO 7176-2:2001, ISO 7176-10:2008. The biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2010.

The flame retardant test of the seat cushion/backrest of both subject device and predicate device is carried out according to the ISO 7176-16 test. Therefore, both devices are assured to be under the same safety level.

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

VIII. Summary of non-clinical testing

➢ Performance testing-bench

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

- Risk Analysis developed in accordance with ISO 14971:2019.
- Software validation
- ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electric

wheelchairs

- ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering space
- ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- ISO 7176-8:2014 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strength
- ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ISO 7176-11:2012 Wheelchairs -- Part 11: Test dummies
- ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces.
- ISO 7176-14:2008 Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods
- ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling.
- ISO 7176-16:2012 Wheelchairs -- Part 16: Resistance to ignition of postural support devices
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25:2013 Wheelchairs - Batteries and chargers for powered wheelchairs
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.

- **Biocompatibility of patient-contacting material**

Biocompatibility Tests are carried out in accordance with lS0 10993-1: 2018, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010).

IX. Summary of clinical testing

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the electric wheelchair to its predicate device.

X. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K113463.