November 18, 2024

Zhejiang Innuovo Rehabilitation Devices Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai, 200122
China

Re: K242471
Trade/Device Name: Power Wheelchair (W5538)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 20, 2024
Received: August 20, 2024

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 (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,

Tushar Bansal -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242471

Device Name

Power Wheelchair (W5538)

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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K242471

510(k) Summary

I. SUBMITTER

Name: Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

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Date prepared: 2024-08-08

II. Device

Device trade name: Power Wheelchair, W5538

Common name: Power Wheelchair

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K231508

Power Wheelchair, W5521

Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

IV. Device description

This Power wheelchair, W5538, 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, anti-tip wheel, frame, controller, motor and drive devices, armrest, push-handle, backrest, seat cushion, footrest, battery box and charger.

The device is powered by a Li-ion Battery pack (24V 12Ah, 288Wh) with 15 Km (9.3 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 user 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 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	Predicate device	Subject device	Discussion/ Conclusion
Manufacturer	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	/
Proprietary name, model	Power Wheelchair, W5521	Power Wheelchair, W5538	/
510(k) number	K231508	K242471	/
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.	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.	Same
Intended user	disabled people with mobility difficulties and elderly people	disabled people with mobility difficulties and elderly people	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	6, including two front wheels	6, including two front	Same

Attribute	Predicate device	Subject device	Discussion/ Conclusion
	and two rear wheels, two anti-tip wheels	wheels and two rear wheels, two anti-tip wheels	
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable.	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable.	Same
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	Automatic electromagnetic brake system	Same
back cushion	Polyester fabric	Polyester fabric	Same
seat cushion	rubber patch cloth and Oxford fabric	rubber patch cloth and Oxford fabric	Same
Armrest	Polyurethane (PU)	Polyurethane (PU)	Same
Differences			
Main frame material	aluminum alloy	Magnesium alloy material	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.
Total mass	25kg	19kg	Different frame material caused different weight of the wheelchair. This difference will not raise any new safety and effectiveness concerns.
Overall Dimension	1040mmX600mmX1020mm	1030mmX605mmX940mm	Minor difference on

Attribute	Predicate device	Subject device	Discussion/ Conclusion
(length*width*height)			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)	390mmX600mmX810mm	360mmX605mmX790mm	
Front wheel size/type	7.8” x 1.9”/ PU Solid tire	6.8" x 1.3"/PU Solid tire	Minor difference on dimension of driven wheel will not cause different performance.
Rear wheel size/type	11.8” x 2.2”/ PU Solid tire	10.5″x 1.4″/ PU Solid tire	
Max speed forward	Up to 5.47 km/h (1.52 m/s), adjustable	Up to 6.1 km/h (1.7 m/s), adjustable	minor difference on max. forwarding speed will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Max Speed backward	Less than 3 km/h (0.9m/s)	Less than 3 km/h (0.6m/s)	minor difference on max. back warding speed will not cause different performance.
Maximum safe operational incline degree	6°	10 °	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.
Braking distance	≤1 m	≤1.2 m	minor difference on braking distance will not cause different performance. Shorter

Attribute	Predicate device	Subject device	Discussion/ Conclusion
			distance for braking will be more safety.
Battery	li-ion battery pack; rechargeable, 24 VDC 10Ah	li-ion battery pack; rechargeable, 24 VDC 12Ah	minor difference on battery capacity will not cause different performance. This difference will not raise any new safety and effectiveness concerns.
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Off-board charger Input: 100-240V, 50/60Hz, 1.1A, Output: 24 Vdc, 2A;	Minor difference on the input current of the charger which will not cause new safety and effectiveness concerns raised.
Max loading weight	136kg	120kg	Minor difference on loading weight will not cause different performance. All safety and performance have been validated according to ISO 7176 series.
Maximum distance of travel on the fully charged battery	10km	15 km	Minor difference on travel distance will not cause different performance. This difference will not raise any new safety and effectiveness concerns
Motor	Brush DC motor; 24VDC; 200W; 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	minor difference on motor power will not cause different performance. Both of the motors are evaluated according to standard ISO 7176-14 and there are no new safety and

Attribute	Predicate device	Subject device	Discussion/ Conclusion
			effectiveness concerns raised due to the difference.
Electronic controller	Micon M7086 controller	DZWN2435-BWL 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 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 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Turning Radius	600 mm	900 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

Attribute	Predicate device	Subject device	Discussion/ Conclusion
			space while the minor difference will not raise any new safety and effectiveness concerns.
Maximum obstacle climbing	40 mm	25 mm	Minor difference 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 7176-2:2017, 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 7176-11:2012, ISO 7176-13:1989, ISO 7176-14:2022, ISO 7176-15:1996, ISO 16840-10:2021, ISO 7176-21:2009, ISO 7176-22:2014, ISO10993-5:2009, ISO 10993-10:2021, ISO 10993-23: 2021, IEC60601-1-2: 2020.

The indications for use 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. 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. Turning radius, 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 and ISO 7176-10.

The flame-retardant test of the seat cushion/ backrest of both subject device and predicate device is carried out according to the ISO 16840-10 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 7176-14:2022 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 16840-10: 2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
- 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 60601-1-2:2020.

➢ Biocompatibility of patient-contacting material

The biocompatibility of the subject device was determined via the declaration of identical tissue-contacting materials to the predicate device, which evaluated biocompatibility according to the ISO 10993-5: 2009 and ISO 10993-10:2010 standards.

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 K231508.