September 18, 2025

Superpi Robot Co., Ltd.
℅ Ivy Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai, SH 200122
China

Re: K252428
Trade/Device Name: Electric Wheelchair (Model P2)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 1, 2025
Received: August 1, 2025

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

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.	K252428

Please provide the device trade name(s).

Electric Wheelchair (Model P2)

Please provide your Indications for Use below.

The electric 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.

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

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K252428

I. SUBMITTER

Name: Superpi Robot Co., Ltd.

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Date prepared: 2025-09-18

II. Device

Device trade name: Electric Wheelchair

Model: Model P2

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

K220747

Power Wheelchair, N5515B

Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

IV. Device description

The Electric wheelchair, Model P2, is an indoor/outdoor, foldable, battery-operated 2-wheel (rear-wheel drive) powered wheelchair. It consists of two parts: the electrical part and the wheelchair main body. The electric part includes brushless motor, electromagnetic brake

system, controller, rechargeable Lithium-Ion battery and off-board battery charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, backrest and seat cushion.

The control system, including the controller handle (joystick), is equipped on the control board that attaches to the one of the arm rests. When the joystick is released, the electromagnetic brakes will be actuated, and the power wheelchair is slowed to a stop.

The electric wheelchair can be folded/ expanded manually. The Left and right handrails (joystick) can be interchange.

V. Indication for use

The electric 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

Tabel 1 General Comparison

Attribute	Subject device	Predicate device	Discussion/ Conclusion
Manufacturer	Superpi Robot Co., Ltd.	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	/
Proprietary name, model	Electric Wheelchair, Model P2	Power Wheelchair, N5515B	/
510(k) number	K252428	K220747	/
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 electric 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	Same

Attribute	Subject device	Predicate device	Discussion/ Conclusion
		elderly people	
Use condition	indoor and outdoor use	indoor and outdoor use	Same

Table 2 Basic Parameters Comparison

Attribute	Subject device	Predicate device	Discussion/ Conclusion
Device length	37.80″ (960mm)	37” (940mm)	Minor difference on wheelchair dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Device width	24.41” (620mm)	24.01” (610mm)	
Stowage length	37.80″ (960mm)	28.35” (720mm)	
Stowage width	24.41” (620mm)	12.20” (310mm)	
Stowage height	16.93” (430mm)	24.01” (610mm)	
Number of wheels	6, including two front wheels and two rear wheels, two anti-tip wheels	6, including two front wheels and two rear wheels, two anti-tip wheels	Same
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
Front wheel size/type	7.87” / PU Solid tire	7"/ PU Solid tire	Minor difference on dimension of driven wheel will not cause different performance.
Rear wheel size/type	8.86”/ PU Solid tire	8.5″/ PU Solid tire	
Total mass	57.3lbs (26kg)	35.3lbs (16kg)	Minor difference on total mass will not raise any new safety and effectiveness concerns.
Main frame material	Carbon fiber material	Carbon fiber material	Same
Folding method	front and rear close	front and rear close	Same

Attribute	Subject device	Predicate device	Discussion/ Conclusion
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
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 2.5A, Output: 29.4 Vdc, 2.8A;	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Minor difference on battery charger do not affect effectiveness and safety performance.
back cushion	Poly(ethylene terephthalate) (PET)	Polyester fabric	Different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of subject devices as biocompatibility complied with ISO 10993 series.
seat cushion	Poly(ethylene terephthalate) (PET)	rubber patch cloth and Oxford fabric	
Armrest	ABS	Polyurethane (PU)	
Max loading weight	300lbs (136kg)	300lbs (136kg)	Same
Maximum obstacle climbing	1.18” (30 mm)	1.57” (40 mm)	Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Max speed forward	Up to 6 km/h, adjustable	Up to 6 km/h, adjustable	Same
Maximum safe operational incline degree	10°	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.
Braking distance	35.4” (0.9 m)	≤59” (1.5 m)	minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.

Attribute	Subject device	Predicate device	Discussion/ Conclusion
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.
Maximum distance of travel on the fully charged battery	10.07mi (16.2km)	9.32mi (15 km)	Minor difference on travel distance will not cause different performance. This difference will not raise any new safety and effectiveness concerns
Motor	Brushless DC motor; 24VDC; 250W; 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	Same
Electronic controller	Brushless dual-drive rocker controller	Brushless dual-drive rocker controller	Same
Turning Radius	32.48” (825mm)	35.43” (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 space while the minor difference will not raise any new safety and effectiveness concerns.

Table 3 Safety Comparison

Attribute	Subject device	Predicate device	Discussion/Conclusion
Biocompatibility	All user directly contacting materials are compliance with ISO 10993-1	All user directly contacting materials are compliance with ISO 10993-1	Same
EMC	ISO 7176-21 & IEC60601-1-2	ISO 7176-21 & IEC60601-1-2	Same
Performance	ISO 7176 series IEC 62133-2	ISO 7176 series	Same
Labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

VII. Summary of substantial equivalence discussion

The proposed device and predicate device are complying to the same ISO standards, 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

7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2022, ISO 7176-15:1996, ISO 16840-10:2021, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2: 2020, IEC 62133-2:2017 and FDA guidance document for wheelchairs.

The proposed device performs in a similar manner to the predicate device. All these tests have corresponding requirements/ control criteria following above mentioned standards. And the test results show that the subject product is substantially equivalent to the predicate device in performance.

The performance testing demonstrates that the subject device is substantially equivalent to the predicate devices regarding Static ability, The Dynamic stability, Brake performance, Theoretical distance range, Dimension and weight, Maximum speed, Dimension of wheel Static, impact and fatigue strengths, Climatic tests, Obstacle-climbing ability, Dummy, friction of test surfaces, Power and control systems, Documentation and labeling, Resistance to ignition, Electromagnetic Compatibility and Electrical Safety, Batteries and chargers.

The biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993 requirements.

The non-clinical laboratory data support the safety and performance of the subject device and demonstrate that the subject device should perform as intended in the specified use conditions.

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 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 – Part 25: 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 due to the low-biocompatibility-risk

materials policy in Attachment G of FDA's 2023 Guidance on "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" was invoked for eligible tissue-contacting materials.

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 K220747.