March 24, 2026

Nanjing CareMoving Rehabilitation Equipment Co.,Ltd
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg., 1500# Century Ave.
Shanghai, 200122
China

Re: K254012
Trade/Device Name: Electric Wheelchair (E201)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 9, 2025
Received: December 15, 2025

Dear Eva Li:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.03.24
12:06:14 -04'00'

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

Enclosure

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.	K254012

Please provide the device trade name(s).

Electric Wheelchair (E201)

Please provide your Indications for Use below.

It 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

1. Applicant Information:

Name: Nanjing CareMoving Rehabilitation Equipment Co.,Ltd

Address: 8701, 8707, Building A4, No.128 Jiangjun Avenue, Jiangning District, Nanjing, Jiangsu, China.

Phone:008615150675891
Contact Person: James Gu
Prepared date: March 17, 2026

2. Device

Trade Name: Electric Wheelchair (E201)

Regulatory Class: Class II

Product Code: ITI

Regulation Number: 21 CFR 890.3860

Regulation Name: Powered Wheelchair

3. Predicate Device:

510(K) Number: K250366

Device Name: Electric Wheelchair (LW01301A07)

4. Device description

The product is a wheelchair which provides transport for the elderly and mobility-impaired individuals.

The maximum loading weight of the device is 100kg.

The wheelchair is a battery powered four wheeled vehicle.

It consists one Li-ion Battery with an off-board battery charger, frame, controllers, motors, seat, back support, control device (including: Power on/off, battery power indicator, horn button, speed indicator, speed up/down button, charging port), two rear wheels, two front wheels, foot support.

The wheelchair can easily fold for transportation or storage.

5. Indication for use

It 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

6. Comparison of the Technological Characteristics with the Predicate Device

Table 1 - General Information Comparison

Item	Subject Device (K254012)	Predicate Device (K250366)	Discussion/ Conclusion
Product Code	ITI	ITI	Same
Regulation No.	21 CFR 890.3860	21 CFR 890.3860	Same
Device classification	Class II	Class II	Same
Product Name	Electric Wheelchair	Electric Wheelchair	Same
Model(S)	LW01301A07	E201	Different, the model difference will not raise safety and effectiveness concerns to the device.
Indication for use	It 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.	It 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
Use Environment	Indoor and outdoor use	Indoor and outdoor use	Same
Patient Population	The device is suitable for disabled people with mobility difficulties and elderly people.	The device is suitable for disabled people with mobility difficulties and elderly people.	Same
Product Structure	Consist of two foldable armrests, a backrest, a seat cushion, a safety belt, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, a piece of Li-ion battery pack, an off-board battery charger, a control panel, and an electric motor controller.	Consist of two foldable armrests, a backrest, a seat cushion, a safety belt, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, two Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.	Same

Driving System	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Number of wheels	4	4	Same
Motor	Brushless DC motor; 24VDC; 250W; 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	Same
Battery	Lithium-ion battery 24V 6Ah*2	Li-ion battery pack; rechargeable, 24 VDC 13Ah	Analysis: Minor difference in battery does not impact safety and effectiveness. The battery has been tested according to IEC 62133 standard.
Battery Charger	Off-board charger Input: 100-240VAC, 50/60Hz, 1.5A Output: 24V, 2.0A	Off-board charger Input: 100-240VAC, 50/60Hz, 1.5A; Output: 24V, 2.0A	Same
Main Frame Material	Aluminum Alloy	Aluminum Alloy	Same
Armrest	PU	PU	Same
Seat cushion & Back cushion	Polyethylene terephthalate (PET)	Nylon	Different, this difference does not impact safety and effectiveness.
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde. Rear wheels: driving wheels to control the speed and direction.	Front wheels: driven wheels suitable for rotation, acceleration, retrograde. Rear wheels: driving wheels to control the speed and direction.	Same
Movement control method	By Joystick control	By Joystick control	Same

Table 2 - Technical Parameters Comparison

Item	Subject Device (K254012)	Predicate Device (K250366)	Comparison
Overall dimension (L*W*H)	1120*620*380(mm)	1120*640*1000mm	Different, this difference does

			not impact safety and effectiveness.

Folded Dimension (L*W*H)	810*600*380(mm)	760*640*460mm	Different, this difference does not impact safety and effectiveness.
Front wheel size/type	8 inch PU Solid tire	8 inch PU Solid tire	Same
Real wheel	12 inch PU Solid tire	12 inch PU Pneumatic tire	Different, this difference does not impact safety and effectiveness.
Braking distance	1.2m	1.2m	Same
Maximum safe operational incline degree	6°	6°	Same
Max speed forward	Up to 6.84 km/h (1.9 m/s), adjustable	Up to 6.84 km/h (1.9 m/s), adjustable	Same
Max speed backward	2.88km/h(0.8m/s)	Less than 3.96 km/h (1.1 m/s)	Different, this difference does not impact safety and effectiveness.
Max loading weight	100kg	120kg	Different, this difference does not impact safety and effectiveness.
Maximum distance of travel on the fully charged battery	15.3km	17.6 km	Different, this difference does not impact safety and effectiveness.
Turning Radius	975mm	958mm	Different, this difference does not impact safety and effectiveness.
Maximum obstacle climbing	40mm	30mm	Different, this difference does not impact safety and effectiveness.

Substantial Equivalence Discussion:

The proposed E201 Electric Wheelchair complies 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 7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 7176-16/ISO 16840-10, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2:2020, IEC TR 60601-4-2:2016, ISO 10993-1:2018, ISO10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021.

The instructions for use, design and technological characteristics of the subject Electric Wheelchair are similar to the predicate device. 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 has been 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. There are minor differences in the subject device including the Battery, Seat cushion, Back cushion, Overall dimensions, Folded dimensions, Rear wheel material, Max speed backward, Max loading weight, Maximum distance of travel on the fully charged battery, Turning radius, and Maximum obstacle climbing. However, all differences have been tested according to ISO 7176 series standards and the test records support its safety and effectiveness. These differences do not impact safety and effectiveness. In conclusion, the subject device is substantially equivalent to the cited predicate device (K250366).

Table 3 - Safety Comparison

Item	Subject Device (K254012)	Predicate Device (K250366)	Discussion/ Conclusion
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and ISO10993-23 requirements.	Complies with ISO 10993-1, FDA Guidance	Same
EMC	IEC 60601-1-2& ISO7176-21	IEC 60601-1-2& ISO7176-21	Same
Performance	ISO7176 series	ISO7176 series	Same
Label and labeling	Conforms to FDA Regulatory requirements	Conforms to FDA Regulatory requirements	Same

Item	Subject Device (K254012)	Predicate Device (K250366)	Discussion/ Conclusion

ISO 7176-1	The Static stability has been determined after the testing according to the ISO 7176- 1, and test results meet its design specification.	The Static stability has been determined after the testing according to the ISO 7176- 1, and test results meet its design specification.	Same

ISO 7176-2	The dynamic stability has been determined after the testing according to the ISO 7176- 2, and test results meet its design specification.	The dynamic stability has been determined after the testing according to the ISO 7176- 2, and test results meet its design specification.	Same
ISO 7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	Same
ISO 7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	Same
ISO 7176-5	The dimensions and mass of the wheelchairs have been determined after the testing according to the ISO 7176-5.	The dimensions and mass of the wheelchairs have been determined after the testing according to the ISO 7176-5.	Same
ISO 7176-6	The maximum speed has been determined after the testing according to the ISO 7176-6.	The maximum speed has been determined after the testing according to the ISO 7176-6.	Same
ISO 7176-7	The seating and wheel dimensions have been determined after the testing according to the ISO 7176-7	The seating and wheel dimensions have been determined after the testing according to the ISO 7176-7	Same
ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	Same
ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9.	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9.	Same
ISO 7176-10	The obstacle-climbing ability of device has been determined after the	The obstacle-climbing ability of device has been determined	Same

	testing according to the ISO 7176-10.	after the testing according to the ISO 7176-10.	
ISO 7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11.	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11.	Same
ISO 7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved.	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved.	Same
ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14.	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14.	Same
ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15.	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15.	Same
ISO 7176-16/ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	Same
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21.	The EMC performance results meet the requirements of ISO 7176-21.	Same
ISO 7176-25	The performance of batteries and chargers for powered wheelchairs meet the requirements of ISO 7176-25	The performance of batteries and chargers for powered wheelchairs meet the requirements of ISO 7176-25	Same

7. Non-clinical performance

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

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 - Part 25: Batteries and chargers for powered wheelchairs.
Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020.
Battery testing in according with IEC 62133-2: 2017+A1:2021

8. Clinical performance

None.

9. Conclusion

Based on the comparison and analysis above, the subject device is substantially equivalent to the predicate device (K250366).