June 24, 2026

Shanghai Waylong Intelligent Technology Co.,Ltd
% Andrew Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai,
China

Re: K260937
Trade/Device Name: Smart Electric Wheelchair (R1-Std-BK, R1-Pro-BK, R1-Ultra-GK, R1-Ultra-WK)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 28, 2026
Received: May 29, 2026

Dear Andrew 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.06.24 12:20:59 -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

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.	K260937

Please provide the device trade name(s).

Smart Electric Wheelchair (R1-Std-BK, R1-Pro-BK, R1-Ultra-GK, R1-Ultra-WK)

Please provide your Indications for Use below.

The device 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 (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

510(k) Summary

Document Prepared Date: 2026-03-18

1. Applicant Information

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Submission Correspondent:
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2. Subject Device

Smart Electric Wheelchair, K260937
Model: R1-Std-BK, R1-Pro-BK, R1-Ultra-GK, R1-Ultra-WK
Classification regulations: 21 CFR 890.3860
Product code: ITI
Classification: Class II

3. Substantial Equivalence Information

Anhui Longway Medical Technology Co., LTD.
Electric Wheelchair (LW01301A07), K250366
Classification regulations: 21 CFR 890.3860
Product code: ITI
Classification: Class II

4. Device Description

The Electric Wheelchair is a battery powered four wheeled vehicle.
The wheelchair can easily fold and unfold for transportation or storage.
The max loading of the device is 125 kg. Only for one person sit.

Model: R1-Std-BK

It consists one Lithium battery with an off-board battery charger, frame, controller, motors, seat, back support, control device (including the battery power indicator, power button, horn button, mute button, speed indicator, speed select button "-", speed select button "+", joystick, light, lighting button, USB port, Battery charger

socket), arm supports, two rear wheels, two casters(front wheels), foot support, anti-tip devices, push handle, safety belt, storage basket.

Model: R1-Pro-BK

It consists one Lithium battery with an off- board battery charger, frame, controller, motors, seat, back support, control device (including the battery power indicator, power button, horn button, mute button, speed indicator, speed select button ".", speed select button "+", joystick, light, lighting button, USB port, Battery charger socket), arm supports, two rear wheels, two casters(front wheels), foot support, anti-tip devices, push handle, safety belt, storage basket, mobile phone stand, arm support bag.

Models: R1-Ultra-GK, R1-Ultra-WK

It consists one Lithium battery with an off-board battery charger, frame, controller, motors, seat, back support, control device (including the battery power indicator, power button, horn button, mute button, speed indicator, speed select button "-", speed select button "+", joystick, light, lighting button, USB port, Battery charger socket), arm supports, two rear wheels, two casters(front wheels), foot support, anti-tip devices, push handle, safety belt, storage basket, head support, mobile phone stand, arm support bag, back support backpack.

5. Indication for Use

The device 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. Product parameter

Elements of Comparison	Subject Device (K260937)	Predicate Device (K250366)	Remark
Manufacturer	Shanghai Waylong Intelligent Technology Co.,Ltd	Anhui Longway Medical Technology Co., LTD.	--
Common or Usual name	Smart Electric Wheelchair	Electric Wheelchair	--
Model(s)	R1-Std-BK, R1-Pro-BK, R1-Ultra-GK, R1-Ultra-WK	LW01301A07	--
Classification	Class II	Class II	S.E.
Classification regulation	21 CFR890.3860	21 CFR890.3860	S.E.
Product code	ITI	ITI	S.E.
Indications 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.	S.E.

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
Intended user	disabled or elderly person limited to a seated position.	disabled or elderly person limited to a seated position.	S.E.
Use condition	indoor and outdoor use	indoor and outdoor use	S.E.
Number of wheels	4, including two front wheels and two rear wheels	4, including two front wheels and two rear wheels	S.E.
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	S.E.
Movement control method	By Joystick control	By Joystick control	S.E.
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	S.E.
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E.
Braking distance	1.4 m	1.2 m	Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.
Maximum safe operational incline degree	8.4° (Seat plane angle) / Max slope tested >10.6°	6°	The subject device supports a slightly higher safe operational incline. It has passed ISO 7176-1, 2, and 3 stability and braking tests at the specified inclines, demonstrating equivalent or better safety.
Armrest	PUR	PUR	S.E.

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
Main frame material	Magnesium Alloy	Aluminum Alloy	Although the materials differ, both are lightweight, high-strength alloys. The subject device has fully passed ISO 7176-8 static, impact, and fatigue strength tests with a 125kg test dummy, ensuring equivalent structural safety.
Back cushion	PET (Polyethylene terephthalate)	Nylon	Different synthetic polymers are used. However, the PET material of the subject device has passed ISO 16840-10 flammability testing. A Biocompatibility Justification is provided, demonstrating no new biological risks. Thus, they are S.E.
Seat cushion	PET (Polyethylene terephthalate)	Nylon	
Overall Dimension (length*width*height)	1040*650*1022mm	1120*640*1000mm	Minor difference on wheelchair dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Folded Dimension (length*width*height)	780mm*650mm*430mm	760*640*460mm	
Front wheel size/type	R1-Std-BK: 200*50mm (Approx 8"), PU Solid Tire R1-Pro-BK, R1-Ultra-GK, R1-Ultra-WK: 200*50mm (Approx 8"), Rubber, Non-Pneumatic hollow Tire	8" x 2"/PU Solid tire	Minor material differences are mitigated. Both are non-inflatable puncture-proof designs. Safety is verified through ISO 7176 stability and obstacle testing. S.E.

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
Rear wheel size/type	R1-Std-BK: 12.5*2.25inch (=317.5*57.15mm), Rubber, Inflatable Tire R1-Pro-BK, R1-Ultra-GK, R1-Ultra-WK: 12.5*2.25inch (=317.5*57.15mm), Rubber, Non-Pneumatic hollow Tire	12"x 2"/ PU Pneumatic tire	Minor material differences are mitigated. Both are non-inflatable puncture-proof designs. Safety is verified through ISO 7176 stability and obstacle testing. S.E.
Max speed forward	Up to 2.3 m/s (8.28 km/h)	Up to 6.84 km/h (1.9 m/s), adjustable	Different max speed forward will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Max Speed backward	0.7 m/s (2.52 km/h)	Less than 3.96 km/h (1.1 m/s)	Different max speed backward will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Max loading weight	125 kg	120 kg	Difference on loading weight will not cause different performance. All safety and performance have been validated with the maximum loading weight.

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
Maximum distance of travel on the fully charged battery	R1-Std-BK, R1-Pro-BK: 10.3km R1-Ultra-GK, R1-Ultra-WK: 21.3km	17.6 km	The subject device complies with ISO 7176-4: 2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range, these differences do not affect safety and effectiveness.
Battery	R1-Std-BK, R1-Pro-BK: Li-ion battery pack; 24V, 9.9Ah R1-Ultra-GK, R1-Ultra-WK: Li-ion battery pack; 24V, 19.8Ah	li-ion battery pack; rechargeable, 24 VDC 13Ah	Minor difference on battery capacity will not cause different performance. Larger battery capacity will contribute to the maximum distance.
Motor	Brushless DC motor; 24VDC, 220W; 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	The subject device utilizes slightly lower power motors. However, it successfully passed all ISO 7176 performance requirements, including maximum speed, obstacle climbing, and incline tests, proving the motor power is sufficient and safe. S.E.
Electronic controller	Brushless motor controller	Brushless motor controller	S.E.
Turning Radius	925 mm	958 mm	The turning capabilities are highly comparable. The subject device's turning space meets all requirements for indoor/outdoor maneuverability as verified by ISO 7176-5. S.E.

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
Maximum obstacle climbing	30 mm	30 mm	S.E.

Substantial Equivalence Discussion:

The proposed device and predicate device are complying to the same ISO standards, ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-7, ISO 7176-8, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 16840-10, ISO 7176-21, ISO 7176-25, ISO 7176-31 and FDA guidance Submission for Power Wheelchair.

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 (tipping angle), The Dynamic stability (Safe Gradient Maximum Gradient), 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 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.

7. Product Performance

Item	Proposed Device	Predicate Device	Results
Biocompatibility	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance	S.E.
EMC	ISO 7176-21, IEC 60601-1-2, IEC 60601-4-2	ISO 7176-21, IEC 60601-1-2, IEC 60601-4-2	S.E.
Performance	ISO 7176 series	ISO 7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Item	Proposed Device	Predicate Device	Results
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.	S.E.
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.	S.E.
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.	S.E.
ISO 7176-4	The theoretical distance	The theoretical distance	S.E.

Item	Proposed Device	Predicate Device	Results
	range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	
ISO 7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5.	The dimensions, mass has been determined after the testing according to the ISO 7176-5.	S.E.
ISO 7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-6.	The dimensions, mass has been determined after the testing according to the ISO 7176-6.	S.E.
ISO 7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7.	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7.	S.E.
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.	S.E.
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.	S.E.
ISO 7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10.	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10.	S.E.
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.	S.E.
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.	S.E.
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.	S.E.
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.	S.E.
ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10:2021.	The performance of resistance to ignition meet the requirements of ISO 16840-10:2021.	S.E.
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.	S.E.

Item	Proposed Device	Predicate Device	Results
ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25.	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25.	S.E.
ISO 7176-31	The lithium-ion battery systems and chargers have been tested and meet the requirements of ISO 7176-31:2023.	N/A	S.E. (The subject device demonstrates compliance with the latest FDA-recognized consensus standard for lithium-ion battery safety, exceeding or matching the safety profile of the predicate).

8. 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 power wheelchair to its predicate device.

9. Conclusion

While there are minor differences between the subject device and the predicate device—specifically regarding the frame material (Magnesium vs. Aluminum alloy), cushion material (PET vs. Nylon), slightly higher maximum speed (2.3 m/s vs. 1.9 m/s), and higher maximum loading weight (125 kg vs. 120 kg)—these differences do not raise any new questions of safety and effectiveness. The subject device has been comprehensively evaluated through bench performance testing (including the complete ISO 7176 series, ISO 16840-10, ISO 7176-31, and IEC 60601-1-2) at its maximum specifications (e.g., tested with a 125kg dummy at maximum speed). The successful test results demonstrate that the subject device manages these structural and operational differences effectively and safely.

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, K250366 Electric Wheelchair from Anhui Longway Medical Technology Co., LTD.

Signature

Jin chunxiang

Typed Name Jin Chunxiang

Date (YYYY-MM-DD) 2026-03-20