July 7, 2026

Yongkang Ruihe Metal Product Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg., 1500# Century Ave.
Shanghai 200122, China

Re: K261164
Trade/Device Name: Electric wheelchair (XW-LY007)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 2, 2026
Received: July 2, 2026

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 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: 2026.07.07
15:46:45 -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.	K261164

Please provide the device trade name(s).

Electric wheelchair (XW-LY007)

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 (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

K261164

I. SUBMITTER

Name:	Yongkang Ruihe Metal Product Co.,Ltd.
Address:	No.99, Huaxi Road, Xicheng Street, Yongkang City, Zhejiang Province, China
Telephone:	008679-87128717
Email:	ykomdzx@gmail.com
Date prepared:	April 2,2026

II. Device

Device trade name: Electric wheelchair
Model: XW-LY007
Common name: Electric wheelchair
Classification name: Powered wheelchair
Regulation class: 2
Regulation number: 21CFR 890.3860
Panel: Physical Medicine
Product code: ITI

III. Predicate device

K252494
Electrically powered wheelchair
Nanjing Kangni Smart Technology Co.,Ltd.

IV. Device Description

The Electric wheelchair mainly consists: a frame (a front wheel bracket, a motor frame, a seat frame, a backrest frame), armrests, a controller, a driver, a seat cushion, a back cushion, footrests, 4 wheels, 2 rear wheel motors, 2 anti-tilt wheels, a safety belt and 2 lead-acid batteries.

The device is composed of two sets of four-bar linkage hinges, which can be unfolded and folded.

The device is installed with an electromagnetic brake that will engage automatically when the device is not in use and the brake cannot be used manually. The device only can be operated on the flat and hard road.

V. 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.

VI. Comparison of technological characteristics with the predicate device

Item	Predicate device	Subject device	Comparison
Manufacturer	Nanjing Kangni Smart Technology Co.,Ltd.	Yongkang Ruihe Metal Product Co.,Ltd.	NA
Proprietary name, model	Electrically powered wheelchair , KZ301B	Electric wheelchair, XW-LY007	NA
510(k) number	K252494	K261164	NA
Device classification name	Class II	Class II	same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	same
Product code	ITI	ITI	same
Indication for use	The Electrically powered 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.	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
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 ,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 Rear wheels: driving wheels 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
Battery charger	Off-board charger Input : 100-240V, 50/60Hz, 1.5A,	Off-board charger Input: 100-240V, 50/60Hz, 3A,	Similar

	DC output: 24V 2A	Output: 24 Vdc, 2A;	
back cushion	Nylon	Nylon	same
seat cushion	Nylon	Nylon	same
Armrest	PUR	Nylon	same
Max loading weight	120Kg	130kg	different
Max obstacle climbing	40mm	15 mm	different
Total mass	35kg	31kg	different
Overall Dimension (length*width*height)(mm)	1120mmX590mmX885mm	930mmX620mmX310mm	Different
Stowage Dimension (length*width*height)(mm)	520mmX590mmX885mm	690mmX650mmX310mm	Different
Front wheel size/type	7.5″ PU Solid Tires	175mm*30mm/ PU Solid tire	Different
Rear wheel size/type	12.5″ PU Solid Tires	290mm*45mm/ PU Solid tire	Different
Max speed forward	Up to 5.9km/h(1.64m/s), adjustable	Up to 6.48 km/h(1.8m/s), adjustable	Different
Max Speed backward	Less than 1.08 km/h (0.3m/s)	Less than 2.16 km/h (0.6m/s)	Different
Maximum safe operational incline degree	9°	6°	Different
Braking distance	≤1 m	≤1 m	Same
Battery	li-ion battery pack; rechargeable, 24 VDC 6Ah	Lead-acid battery; rechargeable, 24 VDC 12Ah	similar
Maximum distance of travel on the fully charged battery	19.8km	18.1km	different
Motor	Brushless DC motor; 24VDC 250W; 2pc	DC decelerating motor; 24VDC; 180W; 2pcs	similar
Turning Radius	950mm	950 mm	Same

Discussion: The difference between the subject device and predicate device will not raise any effectiveness or safety issues since the subject device meet the related requirement of series standard of ISO 7176.

VII. Summary of substantial equivalence discussion

The subject device 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, ISO7176-13:1989, ISO 7176-14:2022, ISO 7176-15:1996, ISO 16840-10: 2021, ISO7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2: 2020, ISO 16840-10:2021

The intended uses for both devices are the same.
The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14:2022.
Software validation is carried out on both control systems.
Brake system are different, it meets the requirements of the ISO 7176-3:2012.
Turning radius 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 flame retardant test of the seat cushion/backrest of the subject device is conducted according to ISO 16840-10. Therefore, both devices are assured to be under the same safety level.
The all rest different between the subject device and predicate device can proved the safety or effectiveness by the ISO 7176 series support reports.
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

- 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 60601-1-2:2014.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

➢ **Biocompatibility of patient-contacting material**

The biocompatibility of the subject device is based on the use of low-biocompatibility risk materials and supporting information in accordance with Attachment G of FDA's 2023 Biocompatibility Guidance.

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 K252494.

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