March 27, 2026

Ningbo Zhishan Medical Technology Co., Ltd.
% Ariel Xiang
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai,
China

Re: K254206
Trade/Device Name: Power wheelchair (ZS-EW8026)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 29, 2025
Received: December 29, 2025

Dear Ariel Xiang:

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: 2026.03.27
10:49:28 -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

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.

510(k) Number *(if known)*
K254206

Device Name
Power wheelchair (ZS-EW8026)

Indications for Use *(Describe)*
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.

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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510(k) Summary

Document Prepared Date: 2025/12/02

Applicant Information:

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Subject Device:

Trade name: Power wheelchair

Classification name: Powered wheelchair

Model:ZS-EW8026

Regulatory Information

Classification: Class II

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

Substantial Equivalence Information:

Zhejiang Cleisman Industry and Trade Co.,LTD

Device Name:Electric Wheelchair

Models: ZH-W001,ZH-W002,ZH-W003

510(K):K250158

Device Description

The product is intended only carry one person and used as a means of transportation for the disabled, the sick and the infirm.

The power wheelchair is classified as class A and the maximum occupant mass is 150kg.

The power wheelchair is a battery powered four wheeled vehicle.

It consists one Lithium battery with an off-board battery charger, frame, controller, motors, seat, back cushion, control system, armrest, two rear wheels, two casters(front wheels), foot pedal, anti-tip devices.

The power wheelchair can easily fold and unfold for transportation or storage.

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.

1. Product Parameter

Table 1 General Comparison

Elements of Comparison	Subject device (K254206)	Predicate Device (K250158)	Remark
Manufacturer	Ningbo Zhishan Medical Technology Co., Ltd	Zhejiang Cleisman Industry and Trade Co.,LTD	--
Common or Usual name	Power Wheelchair	Electric Wheelchair	--
Model(s)	ZS-EW8026	ZH-W001,ZH-W002,ZH-W003	--
Classification	Class II	Class II	Same
Classification regulation	21 CFR890.3860	21 CFR890.3860	Same
Product code	ITI	ITI	Same
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.
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	6,including two front wheels , two rear wheels,two anti-tips	6,including two front wheels , two rear Wheels,two anti-tips	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	0.7m	ZH-W001:≤1.2m ZH-W002:≤1.0m ZH-W003:≤1.0m	Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.
Maximum safe operationalincline degree	10 °	10 °	S.E
Main frame material	Aluminium alloy	ZH-W001:aluminium alloy ZH-W002:aluminium alloy ZH-W003:carbon steel	S.E
Armrest	PUR	PUR	S.E
Back cushion	Nylon	Nylon	S.E

Seat cushion	Nylon	Nylon	S.E
Overall length	990mm	ZH-W001:1130mm ZH-W002:1020mm ZH-W003:1020mm	Minor difference on wheelchair dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Overall width	650mm	ZH-W001:660mm ZH-W002:600mm ZH-W003:600mm	
Folded Dimension (length*width*height)	780*660*770mm	ZH-W001:770mm*650mm*380mm ZH-W002:760mm*600mm*330mm ZH-W003:760mm*600mm*330mm	
Front wheel size/type	8"/PU Solid tire	ZH-W001:200mm*50mm ZH-W002:190mm*30mm ZH-W003:177mm*40mm	Minor difference on dimension of wheels will not cause different performance.
Rear wheel size/type	12″ PU pneumatic tyre	ZH-W001:317mm*57mm ZH-W002:320mm*35mm ZH-W003:272mm*40mm	
Max speed forward	Up to 6 km/h (1.6 m/s), adjustable	ZH-W001:1.8m/s ZH-W002:1.6m/s ZH-W003:1.6m/s	S. E Same as ZH-W002
Max speed backward	0.6m/s	0.5m/s	higher max. backward speed will not impact overall safety
Max loading weight	150kg	120kg (265lbs)	Difference on loading weight will not cause different performance. All safety and performance have been validated with the maximum loading weight.

Maximum distance of travel on the fully charged battery	15.1 km	ZH-W001:14.3 km ZH-W002:13.8 km ZH-W003: 13.8km	It is caused by the size of the wheel, will not cause different performance, The further away the better.
Battery	Li-ion battery pack; 24 VDC 20Ah	li-ion battery pack 24V,12Ah,	the battery capacity will impact the travel distance, which will not cause new safety and effectiveness concerns raised.
Battery charger	Off-board charger Input: 110-240V, 50/60Hz, 1.5A Output: 29.4 Vdc, 2A;	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	S.E
Motor	Brushless DC motor; 24VDC; 250W; 2pcs	Brushless DC motor, 24V,250W, 2pcs	Minor difference on motor power. Both meet the require of ISO 7176-14 standard. It will not cause new safety and effectiveness concerns.
Electronic controller	24V,35A	Brushless dual-drive rocker controller;40A	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

			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 7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Turning Radius	900 mm	ZH-W001:938mm ZH-W002:875mm ZH-W003:875mm	Minor difference on turning radius will not cause new safety and effectiveness concerns.
Maximum obstacle climbing	25 mm	20mm	Minor difference on obstacle climbing will not cause new safety and effectiveness concerns.

Table 2 safety comparison

Item	Subject device	Predicate Device	Results
Biocompatibility	The biocompatibility of the subject device is based on the use of low-risk biocompatible materials in Attachment G of FDA's 2023 Biocompatibility Guidance.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	S.E.
EMC	ISO7176-21 , IEC 60601-1-2,IEC 60601-4-2	ISO7176-21 and IEC 60601-1-2	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Item	Subject device	Predicate Device	Results
ISO7176-1	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.
ISO7176-2	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.
ISO7176-3	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.
ISO7176-4	The theoretical distance range has been	The theoretical distance range has been determined	S.E.

	determined after the testing according to the ISO 7176-4, and test results meet its design specification.	after the testing according to the ISO 7176-4, and test results meet its design specification.	
ISO7176-5	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.
ISO7176-6	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.
ISO7176-7	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.
ISO7176-8	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.
ISO7176-9	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 testsspecified 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.
ISO7176-10	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.
ISO7176-11	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.

ISO7176-13	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.
ISO7176-14	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.
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO7176-15.	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15.	S.E.
ISO16840-10:2021	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 7176-21and IEC60601-1-2.	The EMC performance results meet the requirements of ISO 7176-21.	S.E.
ISO7176-25	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 5and 6 of ISO 7176 -25.	S.E.

2. 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, 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.

3. Product Performance

The following performance data were provided to verify that the proposed 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 - Part 25: Batteries and chargers for powered wheelchairs.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2 and IEC TR 60601-4
- ANSI C63.18-2014 American National Standard Recommended Practice for an On-Site, Ad-Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters
- IEC 62133-2:2017+A1:2021 Secondary cells and batteries containing alkaline or other non- acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems

Biocompatibility of patient-contacting material

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

4. 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.

5. Substantially Equivalency Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, K250158 Electric Wheelchair from Zhejiang Cleisman Industry and Trade Co.,LTD.