April 28, 2025

Zhejiang Cleisman Industry and Trade Co., LTD
℅ Ariel Xiang
Consultant
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K250158
Trade/Device Name: Electric Wheelchair (ZH-W001, ZH-W002, ZH-W003)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 14, 2025
Received: March 14, 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 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,

Julia E. Slocomb -S 2025.04.28 13:29:41 -04'00'

for Heather Dean, PhD
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

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.

Submission Number *(if known)*

K250158

Device Name

Electric Wheelchair (ZH-W001,ZH-W002 ,ZH-W003)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

K250158

Document Prepared Date: 2025/3/11

A. Applicant

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B. Device

Trade Name: Electric Wheelchair

Common Name: Powered wheelchair

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

Regulatory Information

Classification Name: Powered wheelchair
Classification: Class II.

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device

510Knumber: K113463

power wheelchair, PL00l

SUZHOU KD Medical Appliance Co. Ltd.

D. Indications for use of the device

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.

E. Device Description:

This product consists of frame, wheels, seat, armrest, lithium battery, motor and controller with a lightweight and compact design. The seat cushion is detachable. The armrest can be flipped backward, which is convenient for the elderly to move. Users can drive the wheelchair by themselves through the control device.
The wheelchair uses lithium batteries as its power source. The controller controls the drive left/right motor to realize the wheelchair forward, backward and turn functions.
The frame's material of model ZH-W001 and ZH-W002 is aluminium alloy,the model ZH-W003 is carbon steel. The front wheels are driven wheels suitable for rotation, acceleration, retrograde and other actions of the wheelchair. The front wheels movement will be achieved by thrust generated from the rear wheels. The rear wheels are driving wheels to control the speed and direction. The wheels are PU tires.
When in use, the operator drives the motor of the rear wheel by operating the joystick to achieve the rear wheels movement.
The DC motor and brake system are fixed on the rear wheels.
The max loading of the device is 120KG. Only for one person sit.

F. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device (K230964)	Remark
Manufacturer	Zhejiang Cleisman Industry and Trade Co.,LTD	SUZHOU KD Medical Appliance Co. Ltd.	--
Common or Usual name	Electric Wheelchair	Power Wheelchair	--
Model(s)	ZH-W001,ZH-W002,ZH-W003	PL00l	--
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	S.E.

		limited to a seated position.	
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	ZH-W001:≤1.2m ZH-W002:≤1.0m ZH-W003:≤1.0m	1.5 m	Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.
Maximum safe operational incline degree	10 °	9 °	Minor difference on operational incline degree will not cause different performance.
Main frame material	ZH-W001:aluminium alloy ZH-W002:aluminium alloy ZH-W003:carbon steel	Aluminium alloy	S.E ZH:W003 is different.Different material used for frame, that such difference will not

			impact the safety and effectiveness of the subject device as the performance tests are conducted according to ISO 7176 series.
Armrest	PUR	PU	S.E
Back cushion	Nylon	PU foam covered by nylon fabric cloth	S.E
Seat cushion	Nylon	PU foam covered by nylon fabric cloth	S.E
Overall length	ZH-W001:1130mm ZH-W002:1020mm ZH-W003:1020mm	880mm	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	ZH-W001:660mm ZH-W002:600mm ZH-W003:600mm	570mm	
Folded Dimension (length*width*height)	ZH-W001:770mm*650mm*380mm ZH-W002:760mm*600mm*330mm ZH-W003:760mm*600mm*330mm	750*570*400mm	
Front wheel size/type	ZH-W001:200mm*50mm ZH-W002:190mm*30mm ZH-W003:177mm*40mm	6" x 2"/PU Solid tire	Minor difference on dimension of wheels will not cause different performance.
Rear wheel size/type	ZH-W001:317mm*57mm ZH-W002:320mm*35mm ZH-W003:272mm*40mm	8″x 2.4″/ PU Solid tire	
Max speed forward	ZH-W001:1.8m/s ZH-W002:1.6m/s ZH-W003:1.6m/s	Up to 6 km/h (1.6 m/s), adjustable	Minor difference on max speed forward of wheels will not cause different performance.
Max speed backward	0.5m/s(1.8 km/h)	2.4 mph (3.84 km/h)	lower speed on max. backward speed will be more safety.
Max loading weight	120kg (265lbs)	114kg (251lbs)	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	ZH-W001:14.3 km ZH-W002:13.8 km ZH-W003: 13.8km	20 km	It is caused by the size of the wheel, will not cause different performance, The further away the better.
Battery	li-ion battery pack 24V,12Ah,	li-ion battery pack; rechargeable, 24 VDC 20Ah	the battery capacity will impact the travel distance, which will not cause new safety and effectiveness concerns raised.
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Off-board charger Input: 110-240V, 50-60Hz, Output: 24 Vdc, 2A;	S.E
Motor	Brushless DC motor, 24V,250W, 2pcs	Brushless DC motor; 24VDC; 180W; 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	Brushless dual-drive rocker controller;40A	Brushless dual-drive rocker controller	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	ZH-W001:938mm ZH-W002:875mm ZH-W003:875mm	800 mm	Minor difference on turning radius will not cause new safety and effectiveness concerns.
Maximum obstacle climbing	20mm	30 mm	Minor difference on obstacle climbing will not cause new safety and effectiveness concerns.

Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5、ISO10993-10 and ISO10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
EMC	IEC 60601-1-2&ISO7176-21	IEC 60601-1-2&ISO7176-21	SE
Performance	ISO7176 series	ISO7176 series	SE
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	SE

G. 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.

H. Product Performance

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, K113463 Power Wheelchair from SUZHOU KD Medical Appliance Co. Ltd.