



February 17, 2026

Ningbo Shenyu Medical Equipment Co.,Ltd  
% Andrew Wang  
Consultant  
Shanghai SUNGO Management Consulting Co., Ltd.  
14<sup>th</sup> Floor, Dongfang Bldg., 1500# Century Ave.  
Shanghai,  
China

Re: K253599

Trade/Device Name: Electric Wheelchair (W-A807, W-A807L)  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered Wheelchair  
Regulatory Class: Class II  
Product Code: ITI  
Dated: November 18, 2025  
Received: November 18, 2025

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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Tushar Bansal -S**

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.

K253599

?

Please provide the device trade name(s).

?

Electric Wheelchair (W-A807, W-A807L)

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](#))

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## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Correspondent Contact	Mr. Andrew Wang
Correspondent Contact Email	yuanju.wang@sungoglobal.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Electric Wheelchair (W-A807, W-A807L)
Common Name	Powered wheelchair
Classification Name	Wheelchair, Powered
Regulation Number	890.3860
Product Code(s)	ITI

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K250366	Electric Wheelchair	ITI

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Electric Wheelchair is a battery powered four wheeled vehicle.

The model W-A807 consists one Lithium battery with an off-board battery charger, frame, controller, motors, seat, back support, control device (including the battery indicator, power ON/OFF, speed indicator light, decrease speed, increase speed, horn, joystick, charging port), arm supports, two rear wheels(drive wheel), two casters, foot support, anti-tip devices, handle.

The model W-A807L consists one Lithium battery with an off-board battery charger, frame, controller, motors, seat, back support, control device (including the battery indicator, power ON/OFF, speed indicator light, decrease speed, increase speed, horn, lean back, backrest recline, joystick, charging port), arm supports, two rear wheels(drive wheel), two casters, foot support, anti-tip devices, handle, linear actuator.

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

The wheelchair uses lithium battery as its power source. The controller controls the drive left/right motor to realize the wheelchair

forward, backward and turn functions.

The frame of the device is Aluminum. 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 solid PU tires.

When in use, the operator drives the motor of the rear wheel by operating the controller to achieve the rear wheels movement.

The DC Brushed Motor and brake system are fixed on the rear wheels.

The max loading of the device is 136 kg. Only for one person sit.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

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.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The design and technological characteristics of the Electric Wheelchair is similar to the predicate chosen. There are minor differences between the devices including Braking distance, Overall/Folded Dimension, Front/Rear wheel size, Max speed forward/backward, Max loading weight, Maximum distance of travel on the fully charged battery, Battery, Turning Radius, Maximum obstacle climbing, Motor type. All of the parameter with differences have been tested according to ISO 7176 series standards and the test records support its safety and effectiveness. There is no deleterious effect on safety and effectiveness due to the minor differences. Additionally, they do not influence the intended use of the device. And the same materials were used for parts in contact with user. Therefore, the proposed Wheelchair is substantially equivalent (SE) to the Electric Wheelchair.

<b>Elements of Comparison</b>	<b>Subject Device</b>	<b>Predicate Device (K250366)</b>	<b>Remark</b>
Model(s)	W-A807, W-A807L	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.
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

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E
Braking distance	≤1.0 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	6°	6°	S.E
Armrest	PUR	PUR	S.E
Main frame material	Aluminum Alloy	Aluminum Alloy	S.E
Back cushion	Nylon	Nylon	S.E
Seat cushion	Nylon	Nylon	S.E
Overall Dimension (length*width*height)	W-A807: 980*660*950mm W-A807L: 990*660*950mm	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)	W-A807: 780mm*630mm*490mm W-A807L: 770mm*630mm*500mm	760*640*460mm	
Front wheel size/type	8" PU Solid tire	8" x 2"/PU Solid tire	Different sizes of front wheel will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Rear wheel size/type	12.5" * 2.25" PU Solid tire	12"x 2"/ PU Pneumatic tire	Different sizes of rear wheel will not affect safety and performance of the subject device as all related stability tests are

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
			performed according to standard ISO 7176 series.
Max speed forward	Up to 5.04 km/h (1.4 m/s), adjustable	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	Less than 2.52 km/h (0.7 m/s)	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	136 kg	120 kg	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	16.4 km	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	li-ion battery pack; rechargeable, 24V, 20Ah,	li-ion battery pack; rechargeable, 24 VDC 13Ah	Minor difference on battery capacity will not cause different performance. Larger

Elements of Comparison	Subject Device	Predicate Device (K250366)	Remark
			battery capacity will contribute to the maximum distance.
Motor	Brushed Motor, 24VDC, 250W, 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	Although the Subject Device uses brushed motors while the Predicate uses brushless motors, both have identical power ratings (250W) and operating voltages (24VDC). The difference in motor type primarily relates to the commutation method and does not affect the intended use or basic driving performance. The safety and performance of the motors are further validated through compliance with ISO 7176-14 and IEC 60601-1. This difference does not raise new questions of safety and effectiveness.
Electronic controller	Brushless dual-drive rocker controller	Brushless motor controller	S.E
Turning Radius	900 mm	958 mm	Minor difference on Turning Radius will not cause different performance.
Maximum obstacle climbing	15 mm	30 mm	The predicate device and subject device have different dimensions. Both comply with ISO 7176-10:2008 Wheelchairs – Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs.

<b>Item</b>	<b>Proposed Device</b>	<b>Predicate Device</b>	<b>Results</b>
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.

<b>Item</b>	<b>Proposed Device</b>	<b>Predicate Device</b>	<b>Results</b>
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 ofbrakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness ofbrakes 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 range has been determined after the testing according to the ISO 7176-4, and	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and	S.E.

Item	Proposed Device	Predicate Device	Results
	test results meet its design specification.	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	The test dummies used in the testing of ISO 7176 series are	S.E.

Item	Proposed Device	Predicate Device	Results
	meet the requirements of ISO 7176-11.	meet the requirements of ISO 7176-11.	
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 7176-16/ 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.
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.

## 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 Substantially Equivalency Conclusion**

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.

## Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability  
ISO 7176-2: 2017, Wheelchairs - Part 2: Determination of dynamic stability of Powered Wheelchairs  
ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes  
ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electric wheelchairs and wheelchairs for determination of theoretical distance range  
ISO 7176-5, Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space  
ISO 7176-6: 2018, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of Powered Wheelchairs  
ISO 7176-7, 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 strengths  
ISO 7176-9: 2009, Wheelchairs - Part 9: Climatic tests for Powered 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, First edition 1989-08-01, 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 wheelchairs - 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 wheelchairs, and battery chargers  
ISO 7176-25: 2022 Wheelchairs - Part 25: Lead-acid batteries and chargers for powered wheelchairs Requirements and test methods  
IEC 62133-2: 2017/AMD1: 2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems  
IEC 62304: 2006/AMD1: 2015 Medical device software - Software life cycle processes  
IEC 60601-1-2: 2014/AMD1: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests  
IEC TS 60601-4-2: 2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems  
ISO 10993-1: 2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Not Applicable.

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, Electric Wheelchair, model(s): W-A807, W-A807L, is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K250366.