Tuesday, April 8, 2025

Anhui Longway Medical Technology Co., LTD
% Amanda Sun
Senior Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai, Shanghai 200122
China

Re: K250366
Trade/Device Name: Electric Wheelchair (LW01301A07)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 8, 2025
Received: February 10, 2025

Dear Amanda Sun:

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,

Tushar Bansal -S

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

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)*

K250366

Device Name

Electric Wheelchair (LW01301A07)

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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510(k) #: K250366

# 510(k) Summary

Prepared on: 2025-02-08

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
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| Applicant Contact Applicant | Mr. Xie Alan |
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| Correspondent Contact | Ms. Amanda Sun |
| Correspondent Contact Email | jingyu.sun@sungoglobal.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Electric Wheelchair (LW01301A07) |
| 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 |
|---|---|---|
| K220747 | Power Wheelchair | ITI |

## Device Description Summary

21 CFR 807.92(a)(4)

This Electric Wheelchair, model: LW01301A07, is a motor driven, indoor and outdoor transportation vehicle, which a device for assisting action handicapped people and disabled people to move. It is suitable for disabled people with mobility difficulties and elderly people. The device consists of front wheel, drive wheel, frame, controller, motor, armrest, backrest, seat cushion, seatbelt, pedal, battery box and charger.

The device is powered by Li-ion Battery pack with 17.6 Km range, which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet (100-240V, 50/60Hz) when the device is not in use.

The patient can activate the controller handle (joystick) to control the speed and direction of the wheelchair movement. In addition, when the patient releases the joystick, the joystick will return back to the central position and the wheelchair will be automatically stopped soon due to automatic electromagnetic brake system. Once the joystick is activated again move to other position, the

wheelchair will be re-energized.

## 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)

**Comparison with predicate**

**Table 1 General Comparison**

| **Elements of Comparison** | **Subject Device (K250366)** | **Predicate Device (K220747)** | **Remark** |
|---|---|---|---|
| Manufacturer | Anhui Longway Medical Technology Co., LTD. | Zhejiang Innuovo Rehabilitation Devices Co.,Ltd | -- |
| Common name | Electric Wheelchair | Power Wheelchair | -- |
| Model(s) | LW01301A07 | N5515B | -- |
| 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. |
| 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 | 1.2 m | 1.5 m | **Analysis:** Minor difference on Braking distance will not cause new safety and effectiveness concerns are raised as all related stability tests are performed according to standard ISO 7176 series. |
| Maximum safe operational incline degree | 6° | 9° | **Analysis:** Minor difference on safe operational incline degree will not cause new safety and effectiveness concerns are raised as both the static and dynamic stability under specific inclining degree have been evaluated. |
| Armrest | PU | PU | S.E |
| Battery charger | Off-board charger Input: 100-240VAC, 50/60Hz, 1.5A; Output: 24V, 2.0A | Off-board charger Input: 100-240V, 50/60Hz, 1.5A; Output: 24 VDC, 2A; | S.E |
| Main frame material | Aluminum Alloy | Carbon fiber material | **Analysis:** 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. |
| Seat cushion | Nylon | rubber patch cloth and Oxford fabric | **Analysis:** Different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility tests are carried out according to ISO 10993 series. |
| Back cushion | Nylon | Polyester fabric | |

| | | | |
|---|---|---|---|
| Overall Dimension (length*width*height) | 1120*640*1000mm | 940*610*960mm | **Analysis:** Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence. |
| Folded Dimension (length*width*height) | 760*640*460mm | 720*310*610mm | |
| Front wheel size/type | 8" x 2"/PU Solid tire | 7" x 1.75"/PU Solid tire | **Analysis:** 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″x 2″/ PU Pneumatic tire | 8.5″x 2″/ PU Solid tire | **Analysis:** Different sizes and type of rear wheel will not affect the safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series. |
| Max speed forward | Up to 6.84 km/h (1.9 m/s), adjustable | Up to 6 km/h (1.6 m/s), adjustable | **Analysis:** 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 3.96 km/h (1.1 m/s) | Less than 3 km/h (0.5 m/s) | **Analysis:** 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 | 120kg | 136kg | **Analysis:** Difference weight will different on loading not cause performance. Lower loading weight provide less pressure to the chair and easy for the transportation. |

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|---|---|---|---|
| Battery | Li-ion battery pack; rechargeable, 24 VDC 13Ah | Li-ion battery pack; rechargeable, 24 VDC 12Ah | S.E |
| Maximum distance of travel on the fully charged battery | 17.6 km | 15 km | **Analysis:** 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. |
| Motor | Brushless DC motor; 24VDC; 250W; 2pcs | Brushless DC motor; 24VDC; 250W; 2pcs | S.E |
| Electronic controller | Brushless motor controller | Brushless dual-drive rocker controller | S.E |
| Turning Radius | 958mm | 900 mm | **Analysis:** The predicate device and subject device have different dimensions. Both comply with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness. |
| Maximum obstacle climbing | 30mm | 40 mm | **Analysis:** 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. |

**Table 2 safety comparison**

| Item | Subject Device | Predicate Device | Results |
|---|---|---|---|
| Biocompatibility | Comply with ISO 10993-1, FDA Guidance | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | **Analysis:** All user directly contacting materials of |

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| | | | the Subject Device are all selected from Guidance for "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1:Evaluation and testing within a risk management process" Attachment G – Part B What materials are included". |
| EMC | ISO7176-21 & IEC 60601-2-1<br>IEC 60601-4-2 | ISO7176-21 | SE |
| Performance | ISO7176 series<br>IEC 62133-2 | ISO7176 series | SE |
| Label and labeling | Conforms to FDA Regulatory | Conforms to FDA Regulatory | SE |

| Item | Subject Device | Predicate Devices | 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 determined after the testing according to the ISO 7176-4, and test results meet its design specification. | The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification. | S.E. |
| 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. |

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|---|---|---|---|
| ISO7176-6 | 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. |
| 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 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. |
| 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 ISO 7176-15. | The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15. | S.E. |
| ISO7176-16/ ISO 16840-10 | The performance of resistance to ignition meet the requirements of ISO 16840-10. | The performance of resistance to ignition meet the requirements of ISO 7176-16. | 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 Lead-acid batteries and chargers results meet the requirements of ISO 7176-25. | The Lead-acid batteries and chargers results meet the requirements of ISO 7176-25. | S.E. |

## Technological Comparison 21 CFR 807.92(a)(6)

The design and technological characteristics of the Electric Wheelchair is similar to the predicates chosen. There are minor differences between the devices including Braking distance, Maximum safe operational incline degree, Main frame material, Seat cushion, Back cushion, Overall Dimension, Folded Dimension, Front & Rear wheels material & type, Max speed forward, Max Speed backward, Max loading weight, Maximum distance of travel on the fully charged battery, Turning Radius and Maximum obstacle climbing. All of the parameter with difference have been tested according to ISO7176 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 do not influence the intended use of the device. Therefore, the proposed Wheelchair is substantially equivalent (SE) to The Power Wheelchair (K220747).
Different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility tests are carried out according to ISO 10993 series.

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

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 - Part 25: Batteries and chargers for powered wheelchairs.
Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.

The Subject 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 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, Obstacleclimbing ability, Dummy, friction of test surfaces, Power and control systems, Documentation and labeling, Resistance to ignition, Electromagnetic Compatibility and Electrical Safety, Batteries and chargers.
All directly contacting user materials of the Subject Device are listed in Guidance for "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" Attachment G – Part B What materials are included", as exempt from biocompatibility testing in contact with intact skin.
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.

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices, K220747 Power Wheelchair from Zhejiang Innuovo Rehabilitation Devices Co., Ltd.