June 20, 2025

Jinhua Qidian Vehicle Co. Ltd
% Ariel Xiang
Consultant
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K251248
Trade/Device Name: Electric Wheelchair (qdwp-a01,qdwp-b02)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 23, 2025
Received: April 23, 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 2025.06.20 11:44:26 -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

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)*

K251248

Device Name

ELECTRIC WHEELCHAIR (QDWP-A01,QDWP-B02)

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: 2025/4/21

A. Applicant

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B. Device

Trade Name: Electric wheelchair

Common Name: Powered wheelchair

Model(s): QDWP-A01,QDWP-B02

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.

Reference Device

K211647

Electrically Powered Wheelchair,HP358EA

Kunshan Hi-Fortune Health Products Co., Ltd

D. Indications for use of the device

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.

E. Device Description:

This product consists of frame, wheels, seat, armrest, lithium battery, motor and controller with a lightweight and compact design.The wheelchair can easily fold and unfold for transportation or storage.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 QDWP-A01 uses lithium batteries as its power source, The QDWP-B02 uses lead acid batteries as its power source.The controller controls the drive left/right motor to realize the wheelchair forward, backward and turn functions.

The frame of QDWP-A01 is aluminum,the frame of QDWP-B02 is 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. When in use, the operator drives the motor of the rear wheel by operating the joystick to achieve the rear wheels movement.

The 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	Subject Device (K251248)	Predicate Device (K113463)	Reference Device (K211647)	Remark
Manufacturer	JINHUA QIDIAN VEHICLE CO.LTD	SUZHOU KD Medical Appliance Co. Ltd.	Kunshan Hi-Fortune Health Products Co., Ltd	--
Common or	Electric wheelchair	Power Wheelcha	Electrically Powered	--

Usual name			ir	Wheelchair	
Model(s)	QDWP-A01	QDWP-B02	PL00l	HP358EA	--
Classification	Class II		Class II	Class II	Same
Classification regulation	21 CFR890.3860		21 CFR890.3860	21 CFR890.3860	Same
Product code	ITI		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.	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	disabled or elderly person limited to a seated position.	S.E.

		position.		
Use condition	indoor and outdoor use	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	6, including two front wheels and two rear wheels, two anti-tip 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:drive n wheels suitable for rotation, accelerati on, retrograd e Rear wheels: driving wheels to control the speed and direction	Front wheels: driven wheels suitable for rotation, accelera tion, retrograd e Rear wheels: driving wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable	S.E
Movement c ontrol	By Joystick control	By Joystick control	By Joystick control	S.E

method				
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Direct drive on the rear wheels	S.E
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E
Braking distance	1.2m	1.5 m	0.8m	**Analysis:** Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.
Maximum s degree	10 °	9 °	10°	S.E
Armrest	PP	PU	PU	**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.
Main frame material	Aluminium alloy	Steel	Aluminum alloy	Aluminum alloy	QDWP-A01 is

					Same as Predicate Device; QDWP-B02 is different. **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.
Back cushion	Nylon		PU foam covered by nylon fabric cloth	Terylene	**S.E** Same as Predicate Device.
Seat cushion	Nylon		PU foam covered by nylon fabric cloth	Terylene	
Overall length	1120mm	970mm	880mm	990mm	**Analysis:** 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	600mm	660mm	570mm	620mm	
Folded Dimension (length*width*height)	710*600*450mm	680*460*770mm	750*570*400mm	620mmX550mmX850mm	

Front wheel size/type	200mm×50mm PU Solid tire (8 inch)	200mm×45mm (8 inch) PU Solid tire	6" x 2"/PU Solid tire	8" PU tire	S.E Same as Reference Device.
Rear wheel size/type	10inch×2.0inch Rubber Filler	305mm×43mm (12 inch) PU Solid tire	8″x 2.4″/ PU Solid tire	12" Pneumatic tires	DWP-B02 is same as reference device. **Analysis:** Minor difference on dimension of wheels will not cause different performance.
Max speed forward	1.8 m/s (6.5km/h)		Up to 6 km/h (1.6 m/s), adjustable	1.4 m/s	**Analysis:** Minor difference on Max speed forward of

					wheels will not cause different performance.
Max loading weight	120kg		114kg (251lbs)	120kg	S.E
Maximum distance of travel on the fully charged battery	20.3km	10.0km	20 km	10km	S.E
Battery	Lithium-ion Battery 24V, 10Ah,2PCS	Lead Acid Battery, 12V, 12Ah,2PCS	li-ion battery pack; rechargeable, 24 VDC 20Ah	li-ion battery; rechargeable, 25.2VDC, 10.4Ah	**Analysis:** QDWP-A01 is same , QDWP-B02 is different. The performance of batteries and charger of device meet the Requirements of ISO
Battery charger	Off-board charger, Input: 100-240V~1.8A, 50/60Hz Output: 24V, 3.0A	Off-board charger, Input:100/240V,50/60Hz/55W Output:24V-29.6V,1.8A	Off-board charger Input: 110-240V, 50-60Hz, Output: 24 Vdc, 2A;	Off-board charger, Input :100-240VAC, 50-60Hz, 1.2-0.5A DC output: 24Vdc2A	

					7176-25.
Motor	Brushless Motor, 24VDC, 250W	Brushed motor, 24VDC, 250W	Brushless DC motor; 24VDC; 180W; 2pcs	DC Brushed Motor, 24Vdc 250W;2pcs	QDWP-B02 is same as reference device. The type of QDWP-A01 is predicate device. **Analysis:** 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 40A	24V35A	Brushless dual-drive rocker controller	24V 35A	QDWP-B02 is same as reference device. **Analysis**

					: 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	900mm	950mm	800 mm	500mm	**Analysis:**

					Minor difference on turning radius will not cause new safety and effectiveness concerns.
Maximum obstacle climbing	25mm		30 mm	30mm	**Analysis:** 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 ,ISO10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	S.E.
EMC	ISO7176-21 and IEC 60601-1-2	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.

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, ISO7176-22,ISO 7176-25, IEC 60601-1-2 and FDA guidance Submission for Power Wheelchair.

The indications for use, design, structure, composition, principle of operation and energy source of proposed device and predicate device are identical.The dimensions and performance parameters are similar.The main differences are motor and controller.

The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14. Software validation is carried out on both control systems. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3. Turning radius, Maximum obstacle climbing and Maximum safe operational incline are slightly different while such differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns as well as both meet the requirements of the ISO 7176-2 and ISO 7176-10.

The materials in contact with human tissue are identical for both proposed device and predicate device.The biocompatibility of the proposed device and predicate device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2021 & ISO 10993-23: 2021.

The flame-retardant test of the seat cushion/ backrest of both subject device and predicate device is carried out according to the ISO 16840-10 test. Therefore, both devices are assured to be under the same safety level.

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

H. Product Performance

a) Product Material Safety

To ensure the safety of the wheelchair material, the bio-compatibility testing was done to the products. The testing was conducted according to the following standards:

ISO10993-5 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity

ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation

From the test result, we can find the material are safety and can meet the requirements.

b) Performance of the products

The following performance data were provided to verify that the subject 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 proceduresd

ISO 7176-25：2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs.

Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020 8.11.

I. Conclusion

The proposed device and predicate device have the same technological characteristics, features, specifications, materials, mode of operation, and intended use of the device. To ensure all the key characteristic of the products can meet the requirements, the testing was done and all the results indicate the positive conclusion.

Based on the analysis above, we confirm these two products are substantially equivalent.