November 12, 2025

Suzhou Kd Intelligent Device Co., Ltd
% Charles Mack
Principal Engineer
Irc Usa
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K252829
Trade/Device Name: Powered Wheelchair (PL001-9001)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 19, 2025
Received: September 19, 2025

Dear Charles Mack:

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

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)*
K252829

Device Name
Powered Wheelchair, PL001-9001

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 K252829

Preparation Date:	November 1, 2025
Manufacturer's Name and Address:	SUZHOU KD INTELLIGENT DEVICE CO., LTD. NO.36, GuGang Road, ChengXiang Town, TaiCang City, JiangSu Province, China 215400 Tel: 86-512-53110088
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Powered Wheelchair, PL001-9001
Common Name(s):	Powered Wheelchair
Regulation Name(s):	Powered Wheelchair
Regulation Number(s):	21 CFR 890.3860
Primary Product Code:	ITI
Device Class:	Class II
Predicate Device:	21 CFR 890.3860
Device Name:	Power Wheelchair, PL001
Common Name(s):	Powered Wheelchair
Regulation Name(s):	Powered Wheelchair
Regulation Number(s):	21 CFR 890.3860
Primary Product Code:	ITI
Device Class:	Class II

Device Description:

The subject device consists of a frame, wheels, a seat, an armrest, a lithium battery, a motor, and a controller with a lightweight and compact design. The entire wheelchair can be folded, allowing it to be easily carried or rolled after folding. The seat cushion is detachable. The armrest can be flipped upside down, which is convenient for the elderly to move. Users can drive the wheelchair independently by controlling the device.

It uses lithium batteries as its power source. The controller controls the drive left/right motor, enabling the wheelchair to move forward, backward, and turn.

The frame of the device is made of Aluminum Alloy, the same as previously specified in PL001 of K113463. The front wheels are driven wheels that are suitable for rotation, acceleration, and retrograde motion, as well as other actions of the wheelchair. The front wheels' movement will be achieved by the thrust generated from the rear wheels. The rear wheels serve as the driving wheels, controlling speed and direction. The wheels are PU Solid tires. When in use, the operator drives the motor of the rear wheel by operating the controller's joystick to achieve movement of the rear wheel.

The DC brushless motor and brake system are fixed on the rear wheels.

The maximum loading capacity of the device is 136 kg. Only one person can sit.

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.

Characteristics	Subject Device	Predicate Device	Remark
Device	Powered Wheelchair PL001-9001	Power Wheelchair PL001	-
Manufacturer	Suzhou KD Intelligent Device Co., Ltd.	Suzhou KD Intelligent Device Co., Ltd.	Identical
510K	Pending	K113463	-
CFR	890.3860	890.3860	Identical
Product Code	ITI	ITI	Identical
Classification	2	2	Identical
Classification Name	Powered wheelchair	Powered wheelchair	Identical
Indication 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.	The device 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.	Identical
Rx or OTC	OTC	OTC	Identical
Use condition	Indoor and outdoor use	Indoor and outdoor use	Identical
Number of wheels	6, including two front wheels and two rear wheels, two anti-tip wheels	6, including two front wheels and two rear wheels, two anti-tip wheels	Identical
Function of the wheel	Front wheels: Driven wheels suitable for rotation, acceleration, and retrograde Rear wheels: Driving wheels to control the speed and direction	Front wheels: Driven wheels suitable for rotation, acceleration, and retrograde Rear wheels: Driving wheels to control the speed and direction	Identical
Controller	YS-FW-9001	WS-1	*Note 1*
Motor	Brushless DC motor DC24V250W, 2pcs	Brushless DC motor DC24V150W, 2pcs	*Note 2*
Movement control method	By Joystick control	By Joystick control	Identical
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Identical
Brake system	Intelligent regenerative electromagnetic brake	Intelligent regenerative electromagnetic brake	Identical

Characteristics	Subject Device	Predicate Device	Remark
Braking distance	≤1 m	≤1.5 m	*Note 3*
Armrest	PU	PU	Identical
Back cushion	Fabric cloth	Fabric cloth	Identical
Seat cushion	Fabric cloth	Fabric cloth	Identical
Main frame material	Aluminum Alloy	Aluminum Alloy	Identical
Max loading weight	136kg (300 lbs)	114 kg (251 lbs)	*Note 4*
Maximum safe operational incline degree	10°	10°	Identical
Overall Dimension (length*width*height)	980 x 600 x 908 mm	900 x 600 x 880 mm	*Note 5*
Folded Dimension (length*width*height)	750 x 600 x 350 mm	750 x 560 x 380 mm	
Front wheel size/type	8" PU Solid tire	8" PU Solid tire	Identical
Rear wheel size/type	10"PU Solid tires	8" PU Solid tire	*Note 6*
Max speed forward	Up to 6 km/h (1.67 m/s)	Up to 6 km/h (1.67 m/s)	Identical
Max speed backward	Less than 2.5 km/h (0.7 m/s)	Less than 2.5 km/h (0.7 m/s)	Identical
Maximum distance of Travel on the fully charged battery	25km	20 km	*Note 7*
Battery	Li-ion battery pack; rechargeable, 24 VDC 12Ah	Li-ion battery pack; rechargeable, 24 VDC 10Ah	*Note 8*
Battery charger	Off-board charger Input: 100-240V. 50/60Hz Output: 24 Vdc. 2A	Off-board charger Input: 100-220V. 50/60Hz Output: 24 Vdc. 2A	
Turning Diameter	1600 mm (63”)	1600 mm (63”)	Identical
Max obstacle climbing	50 mm (2.0”)	30 mm (1.2”)	*Note 9*
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993	Identical
EMC	Complies with IEC60601-1-2, ISO7176-21	Complies with IEC60601-1-2, ISO7176-21	Identical
Performance	Complies with ISO7176 series	Complies with ISO7176 series	Identical
Labeling	FDA Guidance - Labeling Regulatory Requirements for Medical Devices	FDA Guidance - Labeling Regulatory Requirements for Medical Devices	Identical

Note 1:
The subject device's controller is the updated version of the predicate device's controller from the same supplier; The new version controller is also used in the other FDA-cleared powered wheelchairs, such as K191105, K212092, K241854, K242252, K242448, K242468, etc., and conforms to the same performance standards ISO 7176 requirement as the predicate device. The difference doesn't raise new issues of safety and effectiveness of the subject devices.

Note 2:
The motor power of the subject device is higher than that of the predicate device, resulting in better performance. Still, it conforms to the same safety, EMC, and performance standards as the predicate device. The difference doesn't raise new issues of safety and effectiveness of the subject devices.

Note 3:
The braking distance of the subject device is shorter and better than that of the predicate device, but it conforms to the same performance standards as required by ISO 7176. The difference doesn't raise new issues regarding the safety and effectiveness of the subject device.

Note 4:
The maximum loading weight of the subject device is greater than that of the predicate device, but it conforms to the same performance standards as the predicate device, as required by ISO 7176. The difference doesn't raise new issues of safety and effectiveness of the subject devices.

Note 5:
The dimension of the subject device is not the same as the predicate device, but conforms to the same performance standards ISO 7176 requirement as the predicate device. The difference doesn't raise new issues of safety and effectiveness of the subject devices.

Note 6:
The wheel size of the subject device is slightly larger than that of the predicate device, but it conforms to the same performance standards as the ISO 7176 requirement for the predicate device. The difference doesn't raise new issues of safety and effectiveness of the subject devices.

Note 7:
The maximum distance of the subject device is better and longer than that of the predicate device, but conforms to the same performance standards ISO 7176 requirement as the predicate device. The difference doesn't raise new issues of safety and effectiveness of the subject devices.

Note 8:
The battery and charge specifications of the subject device are slightly different from those of the predicate device, but they conform to the same safety, EMC, and performance requirements.

Note 9:
The maximum obstacle climbing of the subject device is better and longer than that of the predicate device. It conforms to the same performance standards as the ISO 7176 requirement for the predicate device. The difference doesn't raise new issues of safety and effectiveness of the subject devices.

Test Summary:
To establish substantial equivalence to the identified predicate devices, we performed the test below on the subject devices: Powered Wheelchairs PL001 and PL001-9001. The testing results demonstrated that the devices meet the requirements of applicable standards and are substantially equivalent to the predicate devices.

Non-Clinical Study:
Safety and EMC
To verify the basic safety and essential performance of the Powered Wheelchair PL001-9001, we conducted the tests listed below:

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests

Performance Data:

ISO 7176-21 Second edition 2009-04-01 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-1 Third edition 2014-10-01 Wheelchairs - Part 1: Determination of static stability
ISO 7176-2 Third edition 2017-10 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs
ISO 7176-3 Third edition 2012-12-15 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 scooters 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 Third edition 2018-06 Wheelchairs - Part 6: Determination of maximum speed of electrically powered wheelchairs
ISO 7176-7 First Edition 1998-05-15 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
ISO 7176-8 Second edition 2014-12-15 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9 Third edition 2009-11-15 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
ISO 7176-10 Second edition 2008-11-01 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
ISO 7176-11 Second edition 2012-12-01 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 Second edition 2008-02-15 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
ISO 7176-21 Second edition 2009-04-01 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22 Second edition 2014-09-01 Wheelchairs - Part 22: Set-up procedure
ISO 7176-31: 2023 Wheelchairs - Part 31: Lithium-ion battery systems and chargers for powered wheelchairs. Requirements and test methods
ISO 16840-10 Second edition 2021-06 Corrected version 2022-01 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
ISO 14971 Third Edition 2019-12 Medical devices-Application of risk management to medical devices

Software Verification and Validation
Software verification and validation were provided in compliance with FDA Guidance "The Content of the Premarket Submission for Software Contained in Medical Devices." The verifications and validations demonstrate that the subject device works functionally.

Conclusion:
Per the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, the subject device is as safe and effective as and substantially equivalent to the predicate devices described herein.