October 4, 2024

Anhui JBH Medical Apparatus Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1 401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K241854
Trade/Device Name: Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 6, 2024
Received: September 6, 2024

Dear Ivy 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) 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 Rehabilitation 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)*

K241854

Device Name

Power Wheelchair

Indications for Use *(Describe)*

The power wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

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

I. SUBMITTER

Name: Anhui JBH Medical Apparatus Co., Ltd.

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Date prepared: 2024-6-26

II. Device

Device trade name: Power wheelchair

Model: D25

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K113463

Power Wheelchair, PL001

SUZHOU KD Medical Appliance Co. Ltd.

IV. Device description

The D25 power wheelchair is a four wheeled personal mobile device with a complementary chair support system that is powered by two motors. The traveling speed is controlled by the motor, and the traveling direction is controlled by the passenger. This product is a device suitable for disabled people with mobility difficulties and elderly people and it is intended to provide mobility to a disabled or elderly person limited to a seated position. The power wheelchair can be travelled on flat and obstacle ground surface, and direction and speed of

the wheelchair can be controlled by the passenger's hand with the help of the joystick. The device can be used to provide indoor and outdoor mobility at a certain distance but not allowed to be travelled on the road or highway.

The wheelchair (Model D25) has a base with aluminum alloy frame, two front wheels, two rear wheels, a seat, an adjustable steering column, a tiller console, two electric motors, an electromagnetic brake, 1 rechargeable Lithium-Ion Battery with an off-board charger. The movement of the wheelchair is controlled by the rider who operates the throttle lever, speed control dial and handle on the tiller console. The device is installed with an electromagnetic brake that will engage automatically when the wheelchair is not in use and the brake cannot be used manually.

V. Indication for use

The power wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

VI. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicate device	Discussion/Conclusion
Manufacturer	Anhui JBH Medical Apparatus Co., Ltd.	SUZHOU KD Medical Appliance Co. Ltd.	/
Proprietary name, model	Power Wheelchair, D25	power wheelchair, PL00l	/
510(k) number	K241854	K113463	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same
Similarities			
Indication for use	The Power Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	They are 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.	Same
Intended	disabled or elderly person	disabled or elderly person	Same

Attribute	Subject device	Predicate device	Discussion/Conclusion
user	limited to a seated position	limited to a seated position	
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	two pivoting casters: driven wheels suitable for rotation, acceleration, retrograde two rear drive wheels: driving wheels to control the speed and direction	Same
Movement control method	By Joystick control	By Joystick control	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake system	Intelligent electromagnetic brake system	Intelligent regenerative Electromagnetic brake	Same
Max speed forward	Up to 6 km/h (3.75 mph), continuously adjustable	Up to 6 km/h (3.75 mph), variable	Same
Maximum distance of travel on the fully charged battery	20 km	20 km	Same
Main frame material	aluminum alloy, front and rear folding	aluminum alloy, front and rear folding	Same
Armrest cushion	Polyurethane (PU)	PU	Same
Differences			
Overall dimensions (LxWxH)	1030 × 610 × 1010 mm	880 mm×570 mm×890 mm	larger size is designed for bearing more loading weight. All safety and performance have been validated with the maximum rated weight dummy.
Folded dimensions (LxWxH)	610 × 380 × 840 mm	720 mm×570 mm×400 mm	
Ground clearance	120 mm	80 mm	larger ground clearance provides

Attribute	Subject device	Predicate device	Discussion/Conclusion
			better safety performance.
Front wheel size/type	7.9"×2" /PU Solid tire	6″x 2″/PU Solid tire	larger size of driven wheel will provide better stability and safety performance
Rear wheel size/type	12.4"×2.4" /PU Solid tire	8" x 2.4"/PU Solid tire	
Battery	li-ion battery pack; rechargeable, 24 VDC 11.6Ah	Li-ion, Rechargeable; 24 VDC 20Ah	Same rated voltage with different power capacity will not affect the safety and performance of the subject device.
Max Speed backward	0.8 m/s (2.88km/h)	2.4 mph (3.84 km/h)	minor difference on max. backward speed will not cause different performance. lower speed will be more safety.
Minimum braking distance from maximum speed	Forward: 0.9 m	Forward:1.5 m (59")	subject device has shorter braking distance than the predicate device, such differences will not affect safety and performance of the device.
Minimum braking time from maximum speed	0.6 second	Not available	The minimum braking time for our device is 0.6 second, which will ensure the device can be stopped on time as required, and such differences will not affect safety and performance of the device.
Max loading weight	120kg (264 lbs)	114 kg (251 lbs)	minor difference on loading weight will not cause different performance. more loading weight provide more convenient and stable performance for

Attribute	Subject device	Predicate device	Discussion/Conclusion
			the transportation.
Maximum safe operational incline degree	8 °	9 °	minor difference on safe operational incline degree will not cause new safety and effectiveness concerns. Both the static and dynamic stability under specific inclining degree have been evaluated according to standard ISO 7176 series.
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A Output: 24 Vdc, 2A	Off-board, Automatic Type Input: 110-220 V / 50-60 Hz, Output: 24 Vdc, 2A;	More wide range of input voltage in the device which will not cause new safety and effectiveness concerns raised.
Motor	Brush motor; 24VDC; 200W; 2pcs	Brushless DC motor; 24 VDC; 180 W; 2 pcs	minor difference on motor power will not cause different performance. larger power will provide more driving force, no safety and effectiveness concerns raised.
Electronic controller	brush power wheelchair controller	Brushless dual-drive rocker controller	Both of the control systems are evaluated according to standard ISO 7176-14 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Turning Radius	650 mm (25.5")	31.5” (800 mm)	The minor difference in the turning radius will not raise any new safety and effectiveness

Attribute	Subject device	Predicate device	Discussion/Conclusion
			concerns.
Maximum obstacle climbing	20 mm	1.2” (30 mm)	Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.
seat cushion	Sponge foam covered Denim fabric	PU foam covered by nylon fabric cloth	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	Sponge foam covered Denim fabric	PU foam covered by nylon fabric cloth	

VII. Summary of substantial equivalence discussion

The power wheelchair complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-14:2022, ISO 7176-15:1996, ISO 16840-10:2021, ISO 7176-21:2009, ISO 7176-22:2014, ISO10993-5:2009, ISO 10993-10:2021, ISO 10993-23: 2021, IEC60601-1-2: 2020.

The indications for use for both devices are the same. Mainframes of two devices are and the frame materials are the same aluminum alloy. 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 biocompatibility of the subject device is evaluated according to

standard ISO 10993-1 and meet the requirements accordingly.

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.

VIII. Summary of non-clinical testing

➢ Performance testing-bench

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 - Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020.

➢ **Biocompatibility of patient-contacting material**

Biocompatibility Tests are carried out in accordance with ISO 10993-1: 2018, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021) and irritation (ISO 10993-23: 2021). Details of the test summary see biocompatibility summary.

IX. Summary of clinical testing

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the power wheelchair to its predicate device.

X. Conclusions

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K113463.