June 25, 2025

Anhui JBH Medical Apparatus Co., Ltd.
% Kiwi Xu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai,
China

Re: K251606
Trade/Device Name: Power Wheelchair (D26)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: May 27, 2025
Received: May 27, 2025

Dear Kiwi Xu:

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

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.	K251606

Please provide the device trade name(s).

Power Wheelchair (D26)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510k summary

1 SUBMITTER

Name: Anhui JBH Medical Apparatus Co., Ltd.

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Date prepared: 2025.5.23

2 Device

K251606

Device trade name: Power wheelchair

Model: D26

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

3 Predicate device

K242448

Power Wheelchair, D26

Anhui JBH Medical Apparatus Co., Ltd

4 Device description

The power wheelchair, model name:D26, is an indoor/outdoor, foldable, battery-operated 2-wheel (rear-wheel drive) powered wheelchair. It consists of two parts: the electrical part and the wheelchair main body. The electric part includes brushless motor, electromagnetic brake system, controller, rechargeable Lithium-Ion

battery and off-board battery charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, backrest and seat cushion.

The control system, including the controller handle (joystick), is equipped on the control pad that attaches to the one of the arm rests. When the joystick is released, the electromagnetic brakes will be actuated, and the power wheelchair is slowed to a stop.

The power wheelchair, model name: D26, can be controlled by joystick or remote controller via Bluetooth Low Energy (BLE) wireless communication interface. The user can lock and unlock the device remotely via the BLE interface using the remote controller. For safety, controller rocker control is priority over the remote control by design.

The power wheelchair can be folded/ expanded manually. The Left and right handrails (joystick) can be interchange.

5 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.

6 Comparison of technological characteristics with the predicate device

Table 1 General Comparison

Attribute	Subject device	Predicate device	Discussion/Conclusion
Manufacturer	Anhui JBH Medical Apparatus Co., Ltd.	Anhui JBH Medical Apparatus Co., Ltd.	/
Proprietary name, model	Power Wheelchair, D26	power wheelchair, D26	/
510(k) number	-	K242448	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same

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.	The wheelchair (Model: DC01) 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.	Same
Intended user	disabled or elderly person limited to a seated position	disabled or elderly person limited to a seated position	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Type of use	OTC	OTC	Same

Table 2 Basic Parameters Comparison

Attribute	Subject device	Predicate device	Discussion/Conclusion
Device length	1150 mm	1150 mm	Same
Device Width	600 mm	600 mm	Same
Stowage Length	600 mm	600 mm	Same
Stowage width	340 mm	340 mm	Same
Stowage height	810 mm	810 mm	Same
Ground clearance	110 mm	110 mm	Same
Number of wheels	4	4	Same
Front wheel size/type	7" /PU Solid tire	7" /PU Solid tire	Same
Rear wheel size/type	12" /PU Solid tire	12" /PU Solid tire	Same
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	Same
Frame design	The frame of the wheelchair is type capable of front and rear close. The main part of the frame can be folded for saving space and convenient storage and transportation.	The frame of the wheelchair is type capable of front and rear close. The main part of the frame can be folded for saving space and convenient storage and transportation.	Same
Folding mechanism	Manually fold/ expand	Manually fold/ expand	Same

Movement control method	By Joystick control and Bluetooth remote controller	By Joystick control and Bluetooth remote controller	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
Main frame material	Aluminum alloy	Aluminum alloy	Same
Armrest cushion	Polyurethane (PU)	Polyurethane (PU)	Same
Speed settings	5	5	Same
Battery	li-ion battery; rechargeable, 24 VDC 10Ah/ 6Ah*2	li-ion battery; rechargeable, 24 VDC 10Ah/ 6Ah*2	Same
Maximum distance of travel on the fully charged battery	12.8 km	20 km	Minor difference on travel distance will not cause different performance. This difference will not raise any new safety and effectiveness concerns.
Battery charger	Off-board charger Input: 100-240Vac, 50/60Hz, 1.5A Output: 24 Vdc, 2A	Off-board charger Input: 100-240Vac, 50/60Hz, 1.5A Output: 24 Vdc, 2A	Same
Minimum braking distance from maximum speed	Forward: ＜1m	Forward: ＜1m	Same
Max loading weight	180kg	120kg	Minor difference on loading weight will not cause different performance. more loading weight provide more convenient and stable performance for the transportation.
Maximum safe operational incline degree	8 °	8 °	Same

Motor	Brushless motor; 24VDC; 250W; 2pcs	Brushless motor; 24VDC; 250W; 2pcs	Same
Electronic controller	Dual Drive Controller for Brushless Motor	Dual Drive Controller for Brushless Motor	Same
Remote controller	Via Bluetooth	Via Bluetooth	Same
Wireless RF frequency range	2.402 GHz to 2.480 GHz	2.402 GHz to 2.480 GHz	Same
Wireless operation range	10m	10m	Same
Turning Radius	750mm	750mm	Same
Maximum obstacle climbing	25 mm	25 mm	Same
seat cushion/ back cushion	mesh fabric + sponge	mesh fabric + sponge	Same

Table 3 Safety comparison

Attribute	Subject device	Predicate device	Discussion/Conclusion
Biocompatibility	All user directly contacting materials are compliance with ISO 10993-1	All user directly contacting materials are compliance with ISO 10993-1	Same
EMC	ISO 7176-21 & IEC60601-1-2	ISO 7176-21 & IEC60601-1-2	Same
Performance	ISO 7176 series	ISO 7176 series	Same
Labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

7 Summary of substantial equivalence discussion

The proposed device and predicate device are complying to the same ISO standards, 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 7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2022, ISO 7176-15:1996, ISO 16840-10:2021, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2: 2020 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, The Dynamic stability, 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 biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993-5:2009 & ISO10993-10:2010/ ISO 10993-23:2021. Although the standard version updated, test methods for the subject device and the predicate device are same.

8 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.

9 Substantially Equivalence Conclusion

Based on the comparison and analysis above, the subject device is determined to be substantially equivalent to the predicate device, K242448.