December 31, 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: K242468
Trade/Device Name: Power Wheelchair (D10, D12, D15, D17, D20, D37)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 2, 2024
Received: December 2, 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
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K242468

Device Name
Power Wheelchair (D10, D12, D15, D17, D20, D37)

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

K242468

I. SUBMITTER

Name: Anhui JBH Medical Apparatus Co., Ltd.

Address: No. 116 Qicang Road, Industrial District, Ming Guang City, Chuzhou, Anhui, China

Name of contact person: Wei Yuanwei

Telephone: +86-0550-8108866

Fax: +86-0550-8106688

Email: outreach@jbhmedical.com

Date prepared: 2024-12-30

II. Device

Device trade name: Power wheelchair

Models: D10, D12, D15, D17, D20, D37

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K212092

Portable Folding Electric Wheelchair (Model: DC01)

Anhui JBH Medical Apparatus Co., Ltd

Reference device

K223393

Electric Wheelchair (Model: BBR-LY-01-01)

Shanghai BangBang Robotics Co., Ltd.

IV. Device description

The power wheelchair, model name: D10, D12, D15, D17, D20, D37, 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: D10, D12, D15, D17, D20, D37, 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 (Model D10, D12, D15, D17, D20, D37) can be folded/ expanded manually. The Left and right handrails (joystick) can be interchange.

The D17 power wheelchair has an additional headrest and its seat unit can be adjusted by a remote control key to a largest angle of 30°.

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

Table 1 General Comparison

Attribute	Subject device	Predicate device	Reference device	Discussion/Conclusion
Manufacturer	Anhui JBH Medical Apparatus Co., Ltd.	Anhui JBH Medical Apparatus Co., Ltd.	Shanghai BangBang Robotics Co., Ltd.	/
Proprietary name, model	Power Wheelchair D10, D12, D15, D17, D20, D37	power wheelchair, DC01	Electric Wheelchair (Model: BBR-LY-01-01)	/
510(k) number	TBD	K212092	K223393	/
Device classification name	Class II	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	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.	The intended use of the Electric Wheelchair (Model: BBR-LY-01-01) is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.	Same
Intended user	disabled or elderly person limited to a seated position	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	indoor and outdoor use	Same
Type of use	OTC	OTC	OTC	Same

Table 2 Basic Parameters Comparison

Attribute	Subject device	Predicate device	Reference device	Discussion/Conclusion
Device length	950mm – 1110mm	Not publicly available	1075mm	Minor difference on dimension do not affect safety and effectiveness. All safety and performance have been validated with the maximum rated weight dummy.
Device Width	610mm – 660mm	Not publicly available	628mm	
Stowage Length	620mm – 1100mm	Not publicly available	895mm	
Stowage width	280mm – 645mm	Not publicly available	628mm	
Stowage height	260mm -800mm	Not publicly available	395mm	
Ground clearance	50mm - 113mm	Not publicly available	Not publicly available	Minor difference on ground clearance do not affect effectiveness and safety performance. All safety and performance have been validated with the maximum rated weight dummy.
Number of wheels	4	4	4	Same
Front wheel size/type	7" /PU Solid tire for D10, D12, D17, D20, D37 8” /PU solid tire for D15	7" /PU Solid tire	10 in	Minor difference on wheel size do not affect effectiveness and safety

Rear wheel size/type	8" /PU Solid tire for D20, D37 9.6" /PU Solid tire for D15 12.5"/ PU solid tire for D10, D12, D17	8" /PU Solid tire	10 in	performance. All safety and performance have been validated with the maximum rated weight dummy.
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	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.	The frame of the wheelchair is type capable of front and rear close.	Same
Folding mechanism	Manually fold/ expand for model D10, D12, D15, D17, D20, D37 Automatically fold/ expand drove by motor for Model D15	Manually fold/ expand	Automatically fold/ expand drove by motor	Same
Movement control method	By Joystick control and Bluetooth remote controller	By Joystick control	By Joystick control and Bluetooth smartphone app control	Same with reference device, has one more control method through Bluetooth.

Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake system	Intelligent electromagnetic brake system	Intelligent regenerative Electromagnetic brake	Electromagnetic	Same
Max speed forward	Up to 6 km/h (3.75 mph), continuously adjustable	Up to 6 km/h (3.75 mph), variable	6km/h	Same
Armrest cushion	Polyurethane (PU)	Polyurethane (PU)	Not applicable	Same
Speed settings	5	Not publicly available	5	Same
Maximum safe operational incline degree	8 °	8 °	6 °	Same
Electronic controller	Dual Drive Controller for Brushless Motor	Dual Drive Controller for Brushless Motor	Not applicable	Same
Maximum distance of travel on the fully charged battery	20km	20 km	20.6 km	Same
Differences				

Main frame material	Aluminum alloy	Carbon fiber	Not applicable	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.
Battery	li-ion battery; rechargeable, 24 VDC 6Ah*2	Li-ion, Rechargeable; 24 VDC 20Ah	1 rechargeable lithium-ion battery Ratings: 24 V 20Ah	Same rated voltage with different power capacity, both batteries are tested according to IEC62133-2, this difference will not affect the safety and performance of the subject device.
Battery charger	Off-board charger Input: 100-240Vac, 50/60Hz, 1.5A Output: 24 Vdc, 2A	Off-board charger Input: 100-240V, 50/60Hz, 1.5A Output: 24 Vdc, 2A	Input: 100-240VAC 50-60Hz 1.9A Output: 24V 4A	More wide range of input voltage in the device which will not cause new safety and effectiveness concerns raised.
Minimum braking distance from maximum speed	Forward: ＜1m	Forward:0.5m	1.2m	Minor difference on braking distance will not raise any new safety and effectiveness concerns.

Max loading weight	120kg for models D12, D15, D17, D20, D37 140kg for D10	120kg	120kg	Minor difference on loading weight will not cause different performance. more loading weight provide more convenient and stable performance for the transportation.
Motor	Brush motor; 24VDC; 250W/; 2pcs for D10, D12, D17 Brush motor; 24VDC; 180W/; 2pcs for D15, D20, D37	Brushless DC motor; 24 VDC; 180 W; 2 pcs	Not applicable	minor difference on motor power will not cause different performance. larger power will provide more driving force, no safety and effectiveness concerns raised. In addition, although brush motor and brushless motor has some difference, while all safety and performance tests are performed, it will not affect the difference on clinical use.
Remote controller	Via Bluetooth	N/A	Via Bluetooth	Same with reference device

Wireless RF frequency range	2.402 GHz to 2.480 GHz	N/A	2.400GHz ~ 2.4835GHz	Minor difference on the frequency range, however subject device complies with FCC 47 CFR 15.247 and RF exposure requirements, and ISO 7176-12:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, these differences do not affect safety and effectiveness.
Wireless operation range	10m	N/A	10m	Same with reference device
Turning Radius	D20, D37 – 450mm D15, D17– 750mm D12 - 900mm D10 - 934mm	800 mm	760mm	The minor difference in the turning radius is caused by different size of wheelchair and may cause a little bit inconvenience when it turns in a narrow space while the minor difference will not raise any new safety and effectiveness concerns.

Maximum obstacle climbing	20 mm for models D17, D20 25mm for D10, D12 40mm for D37 50mm for D15	20 mm	45mm	Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.
seat cushion/ back cushion	mesh fabric + sponge	linen cloth filled with PU foam	Not applicable	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.

Table 3 Safety comparison

Attribute	Subject device	Predicate device	Reference 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	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	ISO 7176-21	Same
Performance	ISO 7176 series Battery safety testing: IEC 62133-2	ISO 7176 series Battery safety testing: IEC 62133-2	ISO 7176 series	Same
Labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

VII. 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 62133-2:2017, 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.

The proposed device has additional Bluetooth remote control way to operate the wheelchair which is different with the predicate device, while is substantially equivalent to the reference device. Although the remote-control tool is different, the Bluetooth skill is the same. The cybersecurity has been validated to be effective and do not raise new issues of safety or effectiveness.

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.

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
- ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020.

➢ **Biocompatibility of patient-contacting material**

Biocompatibility Tests were 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). Additionally, the low-biocompatibility-risk materials policy in Attachment G of FDA's 2023 Guidance on "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" was invoked for eligible tissue-contacting materials, while the biocompatibility of the footrest was established via claim of identical materials to legally marketed comparator device K241854 (Power Wheelchair).

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 K212092.