October 26, 2026

Anhui JBH Medical Apparatus Co., Ltd.
% Ivy Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dong Fang Bldg., 1500# Century Ave.
Shanghai, 200122
China

Re: K261155
Trade/Device Name: Power Wheelchair (DC07A, DC07S, DC08A, DC08S, DC09, DC09A, DC09S, DC09M, DC10A, DC10S)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 16, 2026
Received: September 17, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K261155

Please provide the device trade name(s).

Power Wheelchair (DC07A, DC07S, DC08A, DC08S, DC09, DC09A, DC09S, DC09M, DC10A, DC10S)

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 (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

K261155

I. SUBMITTER

Name: Anhui JBH Medical Apparatus Co., Ltd.

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Date prepared: 2026-10-22

II. Device

Device trade name: Power wheelchair

Model: DC07A, DC07S, DC08A, DC08S, DC09, DC09A, DC09M, DC09S, DC10A, DC10S

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K242252

Power Wheelchair (Model: DC07L)

Anhui JBH Medical Apparatus Co., Ltd

IV. Device description

The power wheelchair, model name: DC07A，DC07S，DC08A，DC08S，DC09，DC09A，DC09S，DC09M，DC10A, DC10S, 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: DC07A，DC07S，DC08A，DC08S，DC09，DC09A，DC09S，DC09M，DC10A, DC10S, 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 wheelchair can be folded/expanded manually. The Left and right handrails (joystick) can be interchange.

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

The subject wheelchair is similar to the predicate device. Detailed comparison table is listed as below to compare subject technological characteristics of subject device and predicate device on all aspects.

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 DC07A, DC07S, DC08A, DC08S, DC09, DC09A, DC09M, DC09S, DC10A, DC10S	power wheelchair DC07L	/
510(k) number	TBD	K242252	/
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 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.	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

Basic Parameters Comparison

Attribute	Subject device	Predicate device	Discussion/Conclusion
Device length	950-1300mm	950mm	Minor difference on

Device Width	560-630mm	590mm	dimension do not affect safety and effectiveness. All safety and performance have been validated with the maximum rated weight dummy.
Stowage Length	560-990	960mm	
Stowage width	285-600	300mm	
Stowage height	300-790	790mm	
Ground clearance	50-120mm	50mm	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	Same
Front wheel size/type	7”-8" /PU Solid tire	7" /PU Solid tire	larger size of driven wheel will provide better stability and safety performance
Rear wheel size/type	8" – 12”/PU Solid tire	8" /PU Solid tire	
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 or carbon fiber	Carbon fiber	Different material used for the frame and armrest, 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.
Armrest	Polyurethane (PU) or carbon fiber	Polyurethane (PU)	
Speed settings	5	5	Same

Battery	li-ion battery; rechargeable, 24 VDC 12Ah*1 pcs for model DC07A, DC07S, DC08A, DC08S, DC09, DC09A, DC09S, DC10A, DC10S DC09M has 2 pcs of battery	li-ion battery; rechargeable, 24 VDC 12Ah*1pcs	One more battery will support longer travel distance. This difference will not affect the safety and effectiveness of the proposed device.
Maximum distance of travel on the fully charged battery	15.7km - 20km	20 km	Minor difference on travel distance will not cause different performance, no safety and effectiveness concerns raised.
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	200kg for DC09M 150kg for DC07A, DC07S, DC08A, DC08S, DC09, DC09A, DC09S, DC10A, DC10S	150kg	Minor difference on loading weight will not cause different performance. More loading weight provides more convenient and stable performance for the transportation. All safety and performance have been validated with the maximum rated weight dummy. No safety and effectiveness concerns raised.
Maximum safe operational incline degree	8 °	8 °	Same
Motor	Brushless motor; 24VDC; 180W/; 2 pcs - DC07A, DC07S, DC08A, DC08S, DC09, DC09S, DC10A, DC10S Brushless motor; 24VDC; 250W/; 2 pcs - DC09A, DC09M,	Brushless DC motor; 24 VDC; 180W; 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	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	450 - 700mm	450mm	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	25mm	20 mm	Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.
seat cushion/ back cushion	mesh fabric + sponge	mesh fabric + sponge	Same

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 16840-10	ISO 7176 series ISO 16840-10	Same
Labeling	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 7176-31:2023, 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 and ISO 10993-23:2021.

The proposed device has Bluetooth remote control way to operated the wheelchair which is same with the predicate device. The controller system including remote controller and on-board controller is identical to the predicate wheelchair.

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

- Cybersecurity was evaluated per the 2026 FDA guidance document “Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions”.

➢ 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).

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 K242252.