May 27, 2025

Ningbo Baichen Medical Devices Co., Ltd
℅ Luna Hu
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave
Shanghai, 200122
China

Re: K250475
Trade/Device Name: Electric Wheelchair (BC-EA5516, BC-EC8002, BC-EC8003, BC-EALD3)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 30, 2025
Received: February 21, 2025

Dear Luna Hu:

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.

Submission Number *(if known)*

K250475

Device Name

Electric Wheelchair (BC-EA5516, BC-EC8002, BC-EC8003, BC-EALD3)

Indications for Use *(Describe)*

This Electric 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
K250475

Document Prepared Date: 04/30/2025

1. Applicant

Company name: NINGBO BAICHEN MEDICAL DEVICES CO., LTD

Address: Room 2101, No.666 Taikang Middle Road, Yinzhou District, Ningbo City, Zhejiang, 315000, CHINA

Contact Person: Mr. Wu Xiaolong

Tel: alan@baichen.ltd

Submission Correspondent:

Primary Contact: Luna Hu

Shanghai SUNGO Management Consulting Co., Ltd.

14th Floor, Dongfang Building, 1500# Central Ave., Shanghai 200122, China

Tel: 0086-21-58817802

Email: liu.hu@sungoglobal.com

Secondary Contact: Raymond Luo

Shanghai SUNGO Management Consulting Co., Ltd.

14th Floor, Dongfang Building, 1500# Central Ave., Shanghai 200122, China

Tel: 0086-21-68828050

Email: zxfda@sungoglobal.com

2. Device

Trade name: Electric Wheelchair

Classification name: Powered wheelchair

Model: BC-EA5516, BC-EC8002, BC-EC8003, BC-EALD3

Regulatory Information

Classification: Class II

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

3. Predicate Device

Manufacturer: Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

Product Name: Power wheelchair (Model: W5538)

510(K) #: K242471

4. Indication for Use

This Electric 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.

5. Device Description

The product is intended only carry one person and used as a means of transportation for the old and infirm who have difficulty in moving.
The maximum occupant mass is 100kg.
The Electric Wheelchair is a battery powered four wheeled vehicle. It consists one Lithium battery with an off-board battery charger, frame, controller, motors, seat, back support, control device (including the battery power indicator, ON/OFF button, horn button, speed indicator, speed control button, joystick, Battery charger socket), arm supports, two rear wheels, two casters(front wheels), Foot support, anti-tip devices.

The wheelchair can easily fold and unfold for transportation or storage.

6. Non-clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1: 2018 Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
- ISO 7176-1:2014, Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017, Wheelchairs - Part 2: Determination of dynamic stability of electrically powered 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 overall dimensions, mass and manoeuvring space
- ISO 7176-6:2018, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electrically powered 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 strengths
- 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 7176-14:2008, 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 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
- ISO 16840-10: 2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- 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 inportable applications - Part 2: Lithium systems

7. Clinical Test Conclusion

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

8. Comparison technological characteristics with the predicate device

Attribute	Subject device	Predicate device	Results
510(k) number	K250475	K242471	/
Manufacturer	NINGBO BAICHEN MEDICAL DEVICES CO., LTD	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	/
Proprietary name, model	Electric Wheelchair BC-EA5516, BC-EC8002, BC-EC8003, BC-EALD3	Power Wheelchair W5538	/
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	This Electric 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 people with mobility difficulties and elderly people	disabled people with mobility difficulties and elderly people	Same

Use condition	indoor and outdoor use	indoor and outdoor use	Same
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	Same
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable.	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction Anti-tip wheels: preventing the wheelchair from tipping turning over when driving on the slope. Non-adjustable.	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	Automatic electromagnetic brake system	Automatic electromagnetic brake system	Same
Motor	Brushless DC motor; 24VDC; 250W; 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	Same
Differences			
Main frame material	BC-EA5516 and BC-EALD3: Aluminium alloy with ABS coating BC-EC8002 and BC-EC8003: Carbon fiber with PUR coating	Magnesium alloy material	D#1
Total mass	BC-EA5516: 27kg BC-EC8002: 20kg BC-EC8003: 16kg BC-EALD3: 20kg	19kg	D#2
Front wheel size/type	BC-EA5516: Solid tire, 8 inch BC-EC8002: Solid tire, 6 inch BC-EC8003: Solid tire, 6 inch BC-EALD3: Solid tire, 8 inch	6.8" x 1.3"/PU Solid tire	D#3
Rear wheel size/type	BC-EA5516: Pneumatic tire, 12 inch BC-EC8002: Solid tire, 8 inch BC-EC8003: Solid tire, 11 inch BC-EALD3: Solid tire, 12 inch	10.5”x 1.4”/ PU Solid tire	
Max speed forward (km/h)	BC-EA5516: 6.48 BC-EC8002: 6.48 BC-EC8003: 5.76 BC-EALD3: 6.84	Up to 6.1 km/h (1.7 m/s)	D#4

Max speed backward (km/h)	BC-EA5516: 3.24 BC-EC8002: 3.24 BC-EC8003: 2.88 BC-EALD3:3.24	Less than 3 km/h (0.6m/s)	
Maximum safe operational incline degree	BC-EA5516, BC-EC8002 and BC-EC8003: 10°	10°	Same
	BC-EALD3: 6°		D#5
Braking distance	BC-EA5516: 1.2m BC-EC8002: 1.2m	1.2m	Same
	BC-EC8003: 0.7m BC-EALD3: 0.6m		D#6
Battery	li-ion battery pack; rechargeable BC-EA5516: 24V12Ah BC-EC8002: 24V12Ah	li-ion battery pack; rechargeable, 24 VDC 12Ah	Same
	BC-EC8003: 24V10Ah BC-EALD3:XWE2410-B		D#7
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A Output: 24 V, 2A	Off-board charger Input: 100-240V, 50/60Hz, 1.1A Output: 24 V, 2A	D#8
Max loading weight	100kg	120kg	D#9
Maximum distance of travel on the fully charged battery (km)	BC-EC8003: 15	15	Same
	BC-EA5516: 15.7 BC-EC8002: 15.3 BC-EALD3: 18.1		D#10
Electronic controller	SYC-PM30 Controller	DZWN2435-BWL Controller	D#11
Turning Radius (mm)	BC-EA5516: 1000 BC-EC8002: 850 BC-EC8003: 950 BC-EALD3: 850	900	D#12
Maximum obstacle climbing (mm)	BC-EA5516: 40 BC-EC8002, BC-EC8003 and BC-EALD3: 20	25	D#13

Difference analysis：

D#1: 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.

D#2: Different frame material caused different weight of the wheelchair. This difference will not raise any new safety and effectiveness concerns.

D#3: Minor difference on dimension of driven wheel will not cause different performance.

D#4: Minor difference on max. forwarding and back warding speeds will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.

D#5: Minor difference on safe operational incline degree will not cause new safety and effectiveness concerns are raised as both the static and dynamic stability under specific inclining degree have been evaluated according to standard ISO 7176 series.

D#6: Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.

D#7: Minor difference on battery capacity will not cause different performance. This difference will not raise any new safety and effectiveness concerns.

D#8: Minor difference on the input current of the charger which will not cause new safety and effectiveness concerns raised.

D#9: Minor difference on loading weight will not cause different performance. All safety and performance have been validated according to ISO 7176 series.

D#10: Minor difference on travel distance will not cause different performance. This difference will not raise any new safety and effectiveness concerns.

D#11: Similar controller is used, both the control system, including the joystick controller, the electromagnetic brakes and the user interface are similar. The joystick controls the directions and speed of movement, and when the joystick is released, the powered wheelchair will slow down to stop and the brakes will automatically re-engage. The controller also provides the battery status displaying and abnormal condition displaying. 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.

D#12: 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.

D#13: Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.

9. Summary of substantial equivalence discussion

The electric 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, ISO10993-1:2018, IEC60601-1-2: 2020.

The indications for use for both devices are the same. Mainframes of two devices are folded by way of front and rear close. 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 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. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

10. Conclusion

The conclusions 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 K242471.