January 15, 2026

Shanghai BangBang Robotics Co., Ltd.
Yihua Ma
RA Manager
Room 501, Building 3, No.188 Zhongchen Road
Songjiang District
Shanghai, 201613
China

Re: K253276
Trade/Device Name: Electric Wheelchair (Robooter E80) (BBR-E80-01); Electric Wheelchair (Robooter E80) (BBR-E80-02)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 16, 2025
Received: December 16, 2025

Dear Yihua Ma:

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

Tushar Bansal, PhD
Acting 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.	K253276

Please provide the device trade name(s).

Electric Wheelchair (Robooter E80) (BBR-E80-01);
Electric Wheelchair (Robooter E80) (BBR-E80-02)

Please provide your Indications for Use below.

The intended use of the Electric Wheelchair (Robooter E80), Model name: BBR-E80-01 and BBR-E80-02 is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

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)

510(K) Summary

Document Prepared Date: 2025/12/16

K253276

A. Applicant:

Shanghai BangBang Robotics Co., Ltd.

Address: Room 501, Building 3, No.188 Zhongchen Road, Songjiang District, Shanghai, China.

Contact Person:Zephyr Ma

Tel: +86-18616909737

B. Device:

Trade Name: Electric Wheelchair (Robooter E80)

Common Name: Powered wheelchair

Models: BBR-E80-01, BBR-E80-02.

Regulatory Information

Classification Name: Powered wheelchair

Classification: Class II.

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device:

510Knumber: K231868

Device Name: Electric Wheelchair (Robooter E40)

Model: BBR-E40-01

Shanghai BangBang Robotics Co., Ltd.

D. Indications for use of the device:

The intended use of the Electric Wheelchair (Robooter E80), Models name: BBR-E80-01,BBR-E80-02, is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

E. Device Description:

The Electric Wheelchair (Robooter E80), Models name: BBR-E80-01,BBR-E80-02, is an indoor/outdoor, battery- operated, 2-wheel drive (rear-wheel drive) powered wheelchair.

It consists of four modules: seat system, control system, braking system, and drive system. The user sits in the wheelchair seat and uses the control system.

The control pad positioned on the right armrest, user can turn the wheelchair on, control the speed, and direct the movement.

The braking system employs an electromagnetic brake, when release the controller rocker, the electromagnetic brakes will be actuated, and the electric wheelchair will stop in several seconds.

Electromagnetic brake will not take effect immediately, it will take effect after the wheel rotates for 1/2 cycle.

The wheelchair is powered by a 24V DC,12Ah or 20Ah rechargeable lithium-ion battery charged by an offboard lithium-ion battery charger. The wheelchair is driven by two DC motors.

The Electric Wheelchair (Robooter E80), Models name: BBR-E80-01,BBR-E80-02, contains Bluetooth 4.1 BLE technology. The device can be controlled by the controller rocker or remote control by a smartphone app via Bluetooth 4.1 Low Energy (BLE) wireless communication interface. The smartphone app is used to drive the chair remotely. For safety, controller rocker control is priority over the remote control by design. The smartphone app can also view the battery's status, adjust the speed gear level and lock/unlock the unattended device.

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

F. 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 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10: 2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization
ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation
ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
ISO 7176-2:2017, Wheelchairs - Part 2: Determination of dynamic stability of Powered Wheelchairs
ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness ofbrakes
ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electric wheelchairs and wheelchairs for determination of theoretical distance range
ISO 7176-5, Second edition 2008-06-01, 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 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 Powered 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, First edition 1989-08-01, 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 wheelchairs - 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 - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and wheelchairs, and battery chargers
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate Device

Compared to the predicate devices, the subject device has the same intended use, similar product design, similar performance, same safety as the predicate device, the summarized comparison information is listed in the following table

Table 1 General Comparison

Elements of Comparison	Subject Device (K253276)	Predicate Device (K231868)	Remark
Manufacturer	Shanghai Bangbang Robotics Co.,Ltd	Shanghai Bangbang Robotics Co.,Ltd.	Substantially Equivalent (S.E.)

Common or Usual name	Powered Wheelchair	Powered Wheelchair	S.E.
Model(s)	BBR-E80-01,BBR-E80-02	BBR-E40-01	--
Indications for use	The intended use of the Electric Wheelchair (Robooter E80), Models name: BBR-E80-01,BBR-E80-02, is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.	The intended use of the Electric Wheelchair (Robooter E40), Model name: BBR-E40-01 is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered wheelchair.	S.E.
Product code	ITI	ITI	S.E.
Class	II	II	S.E.
Regulation Number	21 CFR 890.3860	21 CFR 890.3860	S.E.
Common name	Wheelchair, Powered	Wheelchair, Powered	S.E.
Type of Use	Over the Counter (OTC Only)	Over the Counter (OTC Only)	S.E.

Table 2 Basic Parameters Comparison

Elements of Comparison	**Subject Device**	**Predicate Device (K231868)**	**Remark**
Models	BBR-E80-01,BBR-E80-02	BBR-E40-01	--
Frame Materiel	Carbon fiber	Alloy	**Analysis:** The predicate device and subject device have different material. Both comply with ISO 7176-1,-2, -3, -4, -5, -6, -7, -8, -9 ,-10 so these differences do not affect safety and effectiveness.
Device Length	1040mm	1000mm	**Analysis:** The predicate device and subject device have different dimensions. Both comply with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness.
Device Width	630mm	624mm	
Device Height	965mm	930mm	
Stowage Length	710mm	700mm	
Stowage Width	630mm	624mm	
Stowage Height	470mm	450mm	

Number of wheels	4	4	S.E.
Front Wheel Diameter	8 in	8 in	S.E.
Rear Wheel Diameter	10 in	10 in	
Charger	Input 100V-240V AC 50-60hz Output:29.4VDC-3A	lnput: 100-240V AC 50/60Hz 2.2A Output: 29.4V DC 3A	S.E.
Maximum Weight Capacity	150kg	150kg	S.E.
Maximum forward speed (maximum safe speed)	8km/h	8km/h	S.E.
Braking System	Electromagnetic	Electromagnetic	S.E.
Braking mechanism in case of electrical Brake Failure	Normally closed brakes be employed. When the device is powered off or when electrical power is lost, the brakes engaged on the motors to prevent rotation.	Normally closed brakes be employed. When the device is powered off or when electrical power is lost, the brakes engaged on the motors to prevent rotation.	S.E.
Minimum braking distance from max speed	150cm	102cm	**Analysis:** Both the subject device and the predicate device comply with ISO 7176-3:2017 Wheelchairs - Part 3: Determination of effectiveness of brakes, so this difference does not affect safety and effectiveness.
Turning Radius	975mm	900mm	**Analysis:** The predicate device and subject device have different dimensions. Both comply with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness.
Obstacle Climbing Height	10mm	40mm	

Drive system	2 Wheel Drive (Rear wheel drive)	2 Wheel Drive (Rear wheel drive)	S.E.
folding mechanism	Manually fold/expand	Manually fold/expand	S.E.
Dynamic Stability	10°	9°	**Analysis:** The predicate device and subject device have different dimensions. Both comply with ISO 7176-2:2017, Wheelchairs - Part 2: Determination of dynamic stability of Powered Wheelchairs so these differences do not affect safety and effectiveness.
On/Off Button	Yes, Power Button on the control pad	Yes, Power Button on the control pad	S.E.
Rocker Location	Right/left can be interchange	Right/left can be interchange	S.E.
Seat Widths	540mm	420mm	**Analysis:** The predicate device and subject device have different dimensions. Both comply with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness.
Seat Depths	420mm	430mm	
Back support Height	520mm	460mm	
Operating Conditions	-10°C~50°C	-10°C~50°C	S.E.
Storage Conditions	-20 ° C~60 ° C	-20 ° C~60 ° C	S.E.
Smartphone App	iOS and Android	iOS and Android	S.E.
Wireless RF frequency range	2.400GHz ~ 2.4835GHz	2.400GHz ~ 2.4835GHz	S.E.
Wireless RF maximum output power	+4dBm~-20dBm (in 4dB steps)	+4dBm~-20dBm (in 4dB steps)	S.E.
Wireless operating range	10m	10m	S.E.
Remote control	Bluetooth only	Bluetooth only	S.E.

Voice function	Notification only	Notification only	S.E.

Table 3 Specific Component Comparison

Elements of Comparison	Subject Device	Predicate Device (K231868)	Remark
Battery pack	1 rechargeable lithium-ion battery Ratings: 12AH (Models: BBR-E80-01) 20AH (Models:BBR-E80-02)	1 rechargeable lithium-ion battery Ratings: 24 V 20Ah	**Analysis**: Both the subject device and the predicate device comply with ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs, so these differences do not affect safety and effectiveness.
Battery weight	2.9kg(12AH) 3.3kg(20AH)	3.4kg	
Driving Range (full battery charge)/ Maximum distance on fully battery charge	13.4km (Models:BBR-E80-01) 21.5km (Models:BBR-E80-02)	21.5km	**Analysis**: Both the subject device and the predicate device comply with ISO 7176-4: 2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range, so these differences do not affect safety and effectiveness.

Substantially Equivalence Discussion:

The design and technological characteristics of the Electric Wheelchair (Robooter E80) is similar to the predicates chosen. There are minor differences between the devices including Folded & Unfolded dimension, Front & Rear wheel diameter, Maximum forward speed (maximum safe speed), Minimum braking distance from max speed, Turning Radius, Obstacle Climbing Height, Battery capacity & weight, Driving Range and Adjustable armrests and backrest. All of the parameter with difference have been tested according to ISO7176 series standards and the test records support its safety and effectiveness. The subject device uses the same user-contacting materials as the predicate device. There is no deleterious effect on safety and effectiveness due to the minor differences do not influence the intended use of the device. Therefore, the proposed Wheelchair is substantially equivalent (SE) to The Electric Wheelchair (Robooter E40) (K231868).

Table 4 Safety comparison

Item	Proposed Device	Predicate Devices	Results
Biocompatibility	the subject device uses the same user-contacting materials as the predicate device	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and ISO 10993-23 requirements.	S.E.
EMC	ISO7176-21 & IEC 60601-2-1	ISO7176-21	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Wireless coexistence	wheelchair conforms to ANSI C63.27-2017	wheelchair conforms to ANSI C63.27-2017	S.E.

Labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Table 5 Safety comparison

Item	Proposed Device	Predicate Devices	Results
ISO7176-1	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	S.E.
ISO7176-2	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification.	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification.	S.E.
ISO7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	S.E.
ISO7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	S.E.
ISO7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5	S.E.
ISO7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-6	S.E.
ISO7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	S.E.
ISO7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	S.E.
ISO7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	S.E.
ISO7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10	S.E.
ISO7176-11	The test dummies used in the testing of ISO 7176 series are meet the	The test dummies used in the testing of ISO 7176 series are meet the	S.E.

	requirements of ISO 7176-11	requirements of ISO 7176-11	
ISO7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	S.E.
ISO7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	S.E.
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	S.E.
ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	S.E.
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	S.E.
ISO7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	S.E.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, Electric Wheelchair (Robooter E80), Models name: BBR-E80-01,BBR-E80-02 is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K231868.