October 31, 2023

Shanghai BangBang Robotics Co., Ltd.
Liu Canfeng
Test and Certification Manager
Room 501, Building 3, No.188 Zhongchen Road
Songjiang District
Shanghai, 201613
China

Re: K231868
Trade/Device Name: Electric Wheelchair (Robooter E40), Model: BBR-E40-01
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 2, 2023
Received: October 2, 2023

Dear Liu Canfeng:

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.

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 Rehabilitation 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231868

Device Name
Electric Wheelchair (Robooter E40), Model name: BBR-E40-01

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

K231868

Prepared Date: Sep. 28,2023

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Shanghai BangBang Robotics Co., Ltd.
Address:	Room 501, Building 3, No.188 Zhongchen Road, Songjiang District, Shanghai 201613 China
Contact person:	Canfeng liu
Title:	Test and Certification Manager
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2. Device Identification

510(K) number:	K231868
Trade/Device Name:	Electric Wheelchair (Robooter E40)
Model:	BBR-E40-01
Common name:	Wheelchair, Powered
Regulation Number:	890.3860
Regulation Name:	Powered wheelchair
Regulation Class:	Class 2
Panel:	Physical Medicine
Product Code:	ITI

3. Predicate Device

510(K) number:	K223393
Trade/Device Name:	Electric Wheelchair
Model:	BBR-LY-01-01
Common name:	Wheelchair, Powered
Regulation Number:	890.3860
Regulation Name:	Powered wheelchair
Regulation Class:	Class 2
Panel:	Physical Medicine
Product Code:	ITI

4. Indication for Use

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.

5. Device Description

The Electric Wheelchair (Robooter E40), Model name: BBR-E40-01 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 panel positioned on the right or left armrest allows the user to turn the wheelchair on, control the speed, and direct the movement.

The braking system employs an electromagnetic brake. When the controller rocker is released, the electromagnetic brakes will be actuated, and the electric wheelchair will stop in several seconds. The 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, 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 E40), Model name: BBR-E40-01 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.

6. Compared to Predicate Device

Compared to the predicate device, the subject device has the same intended use, similar product design, and similar performance. The summarized comparison information is listed in the following table:

SE Comparisons	**Subject Device** Electric Wheelchair (Robooter E40) (Model: BBR-E40-01)	**Predicate Device** Electric Wheelchair (Model: BBR-LY-01-01)	**Similarities/ Differences**
510(K) number	K231868	K223393	/
Indication for Use	The intended use of the Electric Wheelchair (Robooter E40), Model name: BBR-E40-01 is to provide outdoor and indoor mobility to persons	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	Same

	limited to a seated position that are capable of operating a powered wheelchair.	capable of operating a powered wheelchair.	
Product code	ITI	ITI	Same
Class	II	II	Same
Regulation Number	21 CFR 890.3860	21 CFR 890.3860	Same
Common name	Wheelchair, Powered	Wheelchair, Powered	Same
Type of Use	Over the Counter (OTC Only)	Over the Counter (OTC Only)	Same
Device Length	1000 mm	1075 mm	Different See Note 1
Device Width	624mm	628 mm	Different See Note 1
Device Height	930mm	930 mm	Same
Stowage Length	700mm	895 mm	Different See Note 1
Stowage Width	624mm	628 mm	Different See Note 1
Stowage Height	450mm	395 mm	Different See Note 1
Number of wheels	4	4	Same
Front Wheel Diameter	8 in	10 in	Different See Note 2
Rear Wheel Diameter	10 in	10 in	Same
Battery pack	1 rechargeable lithium-ion battery Ratings: 24 V 20Ah	1 rechargeable lithium-ion battery Ratings: 24 V 20Ah	Same
Battery weight	3.4kg	3.4kg	Same
Charger	Input: 100-240V AC 50/60Hz 2.2A Output: 29.4V DC 3A	Input: 100-240VAC 50-60Hz 1.9A Output: 24V DC 4A	Different See Note 3
Maximum Weight Capacity	150kg	120kg	Different See Note 4
Maximum forward speed (maximum safe speed)	7.1km/h	6km/h	Different See Note 5
Speed Settings	5	5	Same
Braking System	Electromagnetic	Electromagnetic	Same
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	Normally closed brakes be employed. When the device is powered off or when electrical power is lost, the brakes engaged on	Same

	the motors to prevent rotation.	the motors to prevent rotation.	
Minimum braking distance from max Speed	102cm	120cm	Different See Note 6
Turning Radius	450mm	380 mm	Different See Note 1
Obstacle Climbing Height	40mm	45mm	Different See Note 1
Ground clearance	65 mm	64 mm	Similar. See Note 1.
Drive system	2 Wheel Drive (Rear wheel drive)	2 Wheel Drive (Rear wheel drive)	Same
Folding mechanism	Manually fold/expand	Automatically fold/ expand drove by motor	Different See Note 7
Dynamic Stability	9°	6°	Different See Note 8
Driving Range (full battery charge)/ Maximum distance on fully battery charge	21.5km	20.6km	Different See Note 4

On/Off Button	Yes, Power Button on the control pad	Yes, Power Button on the control pad	Same
rocker Location	Right/left can be interchange	Right arm	Different The location of rocker does not affect safety and effectiveness
Seat Widths	420mm	425mm	Different See Note 2
Seat Depths	430mm	425mm	Different See Note 2
Back support Height	460mm	455mm	Different See Note 2
Operating Conditions	-10°C~50°C	-10°C~50°C	Same
Storage Conditions	-20 ° C~60 ° C	-40 ° C~60 ° C	Different See Note 9
Smartphone App	iOS and Android	iOS and Android	Same
Wireless RF frequency range	2.400GHz ~ 2.4835GHz	2.400GHz ~ 2.4835GHz	Same
Wireless RF maximum output power	+4dBm~-20dBm (in 4dB steps)	+4dBm~-20dBm (in 4dB steps)	Same
Wireless operating range	10m	10m	Same
Non clinical testing			
Performance	wheelchair conforms to the ISO 7176 standards	wheelchair conforms to the ISO 7176 standards	Same
Flammability Testing	wheelchair conforms to the ISO 7176-16 standards	wheelchair conforms to the ISO 7176-16 standards	Same
Biocompatibility	wheelchair conforms to ISO 10993-5:2009,ISO 10993-10:201 and ISO 10993-23:2021	wheelchair conforms to ISO 10993-5:2009 and ISO 10993-10:2010	Different See Note 10
EMC	wheelchair conforms to ISO 7176-21:2009	wheelchair conforms to ISO 7176-21:2009	Same

Wireless coexistence	wheelchair conforms to ANSI C63.27-2017	wheelchair conforms to ANSI C63.27-2017	Same

Note 1: 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.

Note 2: Both the subject device and the predicate device comply with ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, so these differences do not affect safety and effectiveness.

Note 3: The battery charger of both the subject device and predicate device complies with ISO 7176-25: 2013 Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs, so these differences do not affect safety and effectiveness.

Note 4: 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.

Note 5: Both the subject device and the predicate device comply with ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs, so these differences does not affect safety and effectiveness.

Note 6: 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.

Note 7: The subject device can be folded/expanded manually, the folding mechanism can bear the specified mass in the intended environment, and it does not cause mechanic or other hazards, so this difference does not affect safety and effectiveness.

Note 8: Both the subject device and the predicate device comply with ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs, so the noted difference does not affect safety and effectiveness.

Note 9: Both the subject device and the predicate device comply with ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs. These differences do not affect safety and effectiveness.

Note 10: Both the subject device and the predicate device evaluated biocompatibility according to ISO 10993 series standards. Although the standard version updated, test methods for the subject device and the predicate device are same.

The subject device and predicate device are substantially equivalent in the areas of technological characteristics such as basic design, features, energy source, method of operation, general function, application, and intended use. The subject device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

8. Performance Testing Summary

The subject device Electric Wheelchair (Model: BBR-E40-01) comply with:

Clinical test:

Clinical testing is not required.

Non-clinical data

Safety and performance

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 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 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 7176-16:2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices
ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs

EMC

ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

Wireless Co-existence

ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

Biocompatibility

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

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Electric Wheelchair (Robooter E40), Model name: BBR-E40-01 is as safe, as effective, and performs as well as the legally marketed predicated device Electric Wheelchair (Model: BBR-LY-01-01) K223393.