March 15, 2023

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

Re: K223393
Trade/Device Name: Electric Wheelchair (Model: BBR-LY-01-01)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 29, 2023
Received: February 2, 2023

Dear Canfeng Liu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

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)*
K223393

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

Indications for Use *(Describe)*
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.

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

K223393

Prepared Date: Jan. 29,2023

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
E-mail:	liucf@bangbangrobotics.com
Tel:	86-13524910052

2. Device Identification

510(K) number:	K223393
Trade/Device Name:	Electric Wheelchair
Models:	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

3. Predicate Device

510(K) number:	K213383
Device Name:	WHILL Model C2
Manufacturer:	Whill, Inc.
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 (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.

5. Device Description

The Electric Wheelchair (Model: BBR-LY-01-01) 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 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,20Ah rechargeable lithium-ion battery charged by an offboard lithium-ion battery charger. The wheelchair is driven by two DC motors.

The Electric Wheelchair (Model: BBR-LY-01-01) 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 automatically.

6. Compared to 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

SE Comparisons	**Proposed Device** Electric Wheelchair (Model: BBR-LY-01-01)	**Primary Predicate Device** WHILL Model C2	**Similarities/ Differences**
510(K) number	K223393	K213383	/
Indication for Use	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	The intended use of the Model C2 powered wheelchair is to provide outdoor and indoor mobility to persons limited to a seated position that are capable	Same

SE Comparisons	**Proposed Device** Electric Wheelchair (Model: BBR-LY-01-01)	**Primary Predicate Device** WHILL Model C2	**Similarities/ Differences**
	position that are capable of operating a powered wheelchair.	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	895 mm (Stowage) 1075 mm	38.8 in (985.5mm)	Different See Note 1
Device Width	628 mm	21.8 in (553.7mm)	Different See Note 1
Device Height	395 mm (Stowage) 930 mm	29.3 – 37.2in (744-945mm)	Different See Note 1
Stowage Length	895 mm	/	Different See Note 1
Stowage Width	628 mm	/	Different See Note 1
Stowage Height	395 mm	/	Different See Note 1
Number of wheels	4	4	Same
Front Wheel Diameter	10 in	10.11 in	Different See Note 2
Rear Wheel Diameter	10 in	10.43in	Different See Note 2
Ground Clearance	64 mm	3 in (76mm)	Different See Note 2
Battery pack	1 rechargeable lithium-ion battery Ratings: 24 V 20Ah	1 rechargeable lithium-ion battery Ratings: 25.3 V 10.5Ah	Different See Note 3
Battery weight	3.4kg	6.0 lbs.(2.72kg)	Different See Note 3
Charger	Input: 100-240VAC 50-60Hz 1.9A Output: 24V 4A	Type: off-board Rated DC output voltage: 24.9V DC Rated current output: 2.4A DC	Different See Note 3
Maximum Weight Capacity	120kg	300lb (136kg)	Different See Note 4

SE Comparisons	**Proposed Device** Electric Wheelchair (Model: BBR-LY-01-01)	**Primary Predicate Device** WHILL Model C2	**Similarities/ Differences**
Maximum forward speed (maximum safe speed)	6km/h	5 mph (8km/h)	Different See Note 5
Speed Settings	5	4	Different See Note 5
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 the motors to prevent rotation.	Normally closed brakes (The “normally closed” brakes are by default engaged on the motors, preventing rotation, when the device is powered off or when electrical power is lost.	Same
Minimum braking distance from max speed	120cm	1500 mm (1.5 m)	Different See Note 6
Turning Radius	760mm	30in(762mm)	Different See Note 1
Obstacle Climbing Height (Highest curb clearance)	45mm	2in(50mm)	Different See Note 1
Drive system	2 Wheel Drive (Rear wheel drive)	2 Wheel Drive (Rear wheel drive)	Same See Note 7
folding mechanism	Automatically fold/unfold drove by motor	Without folding mechanism, the seat height can be adjusted manually	Same See Note 8
Dynamic Stability	6°	Measured posteriorly: 10º Measured anteriorly: 10º Measured sideways: 10º	Same See Note 9
Driving Range (full battery charge)/ Maximum distance on fully battery charge	20.6km	11 miles (17.7km)	Different See Note 4

SE Comparisons	**Proposed Device** Electric Wheelchair (Model: BBR-LY-01-01)	**Primary Predicate Device** WHILL Model C2	**Similarities/ Differences**
On/Off Button	Yes, Power Button on the control pad	Yes, Power Button on the control pad.	Same
rocker Location	Right arm	Left or right arm	Different The location of rocker does not affect safety and effectiveness
Seat Widths	425mm	16in(406mm), 18in(457mm) and 20in(508mm)	Different See Note 10
Seat Depths	425mm	16in(406mm), 18in(457mm) and 20in(508mm)	Different See Note 10
Back support Height	455mm	13.4in(340mm)–18(460mm)	Different See Note 10
Tail lamps (2)	White LED lights	Red LED lights	Different See Note 11
Operating Conditions	-10°C~50°C	5 to 104 degrees F (-15 to 40 degrees C)	Different See Note 12
Storage Conditions	-40 ° C~60 ° C	5 to 104 degrees F (-15 to 40 degrees C)	Different See Note 12
Smartphone App	iOS and Android	iOS and Android	Same
Wireless RF frequency range	2.400GHz ~ 2.4835GHz	2.402 GHz to 2.480 GHz	Different See Note 13
Wireless RF maximum output power	+4dBm~-20dBm (in 4dB steps)	5dBm	Different See Note 13
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	conforms to ISO 8191-1/8191-2 that is equivalent to ISO 7176-16	Same
Biocompatibility	wheelchair conforms to ISO 10993-5:2009 and ISO 10993-10:2010	wheelchair conforms to ISO 10993-5:2009 and ISO 10993-10:2010	Same

SE Comparisons	**Proposed Device** Electric Wheelchair (Model: BBR-LY-01-01)	**Primary Predicate Device** WHILL Model C2	**Similarities/ Differences**
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 cannot be folded and can be disassembled, so it has no stowage dimension. The subject device can be folded and cannot be disassembled. The subject device complies with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space, these differences do not affect safety and effectiveness.

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

Note 3: The battery and battery charger comply with ISO 7176-25: 2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs, these differences do not affect safety and effectiveness.

Note 4: The subject device complies with ISO 7176-4: 2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range, these differences do not affect safety and effectiveness.

Note 5: The subject device complies with ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs, these differences do not affect safety and effectiveness.

Note 6: The subject device complies with ISO 7176-3:2017 Wheelchairs - Part 3: Determination of effectiveness of brakes, this difference do not affect safety and effectiveness.

Note 7: The subject device complies with ISO 7176-14:2008 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods, do not affect safety and effectiveness.

Note 8: The subject device complies with ISO 7176 series standard, the folding mechanism can bear the specify mass in intended environment, and it could not cause mechanic or other hazards, so this difference does not affect safety and effectiveness.

Note 9: The subject device complies with ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs, do not affect safety and effectiveness.

Note 10: The subject device complies with ISO 7176- 7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, these differences do not affect safety and effectiveness.

Note 11: The subject device employs a white LED light, the color is different from predicate device, its function is that a wheelchair user can be seen, so this do not affect safety and effectiveness.

Note 12: The subject device complies with ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, these differences do not affect safety and effectiveness.

Note 13: The subject device complies with FCC 47 CFR 15.247 and RF exposure requirements, ANSI C63.27 wireless coexistence and ISO 7176-12:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, these differences do not affect safety and effectiveness.

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 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-LY-01-01) 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
IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

FCC RF

FCC CFR TITLE 47 PART 15 SUBPART C
FCC CFR TITLE 47 PART 2.1093

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 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Electric Wheelchair (Model: BBR-LY-01-01) is as safe, as effective, and performs as well the legally marketed predicated device WHILL Model C2 (K213383).