

# 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

## K223393

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### 1. Submitter's Information

The submitter of this pre-market notification is:

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### 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

<b>SE Comparisons</b>	<b>Proposed Device</b> Electric Wheelchair (Model: BBR-LY-01-01)	<b>Primary Predicate Device</b> WHILL Model C2	<b>Similarities/ Differences</b>
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

<b>SE Comparisons</b>	<b>Proposed Device</b> Electric Wheelchair (Model: BBR-LY-01-01)	<b>Primary Predicate Device</b> WHILL Model C2	<b>Similarities/ Differences</b>
	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

<b>SE Comparisons</b>	<b>Proposed Device</b> Electric Wheelchair (Model: BBR-LY-01-01)	<b>Primary Predicate Device</b> WHILL Model C2	<b>Similarities/ Differences</b>
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: 10° Measured anteriorly: 10° Measured sideways: 10°	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

<b>SE Comparisons</b>	<b>Proposed Device</b> Electric Wheelchair (Model: BBR-LY-01-01)	<b>Primary Predicate Device</b> WHILL Model C2	<b>Similarities/ Differences</b>
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
<b>Non clinical testing</b>			
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

<b>SE Comparisons</b>	<b>Proposed Device</b> Electric Wheelchair (Model: BBR-LY-01-01)	<b>Primary Predicate Device</b> WHILL Model C2	<b>Similarities/ Differences</b>
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 maneuvering 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.

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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).