September 15, 2023

Ningbo Baichen Medical Devices Co., Ltd.
% Jarvis Wu
Consultant
Shanghai Sungo Management Consulting Company Limited
14th floor, 1500# Century Ave.,
Shanghai, Shanghai 200122
China

Re: K232121
Trade/Device Name: Power wheelchair (Model:BC-EA8000)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 17, 2023
Received: July 17, 2023

Dear Jarvis Wu:

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)*
K232121

Device Name
Power wheelchair (BC-EA8000)

Indications for Use *(Describe)*
The Power wheelchair BC-EA8000 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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Ningbo Baichen Medical Devices Co., Ltd.
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510(K)
Summary
K232121

Document Prepared Date: 2023/9/14

A. Applicant:

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B. Device:

Trade Name: Power wheelchair

Common Name: Powered wheelchair

Model: BC-EA8000

Regulatory Information

Classification Name: Powered wheelchair

Classification: Class II.

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device:

510Knumber: K220747

Device Name: Power Wheelchair

Model: N5515B

Zhejiang Innuovo Rehabilitation Devices Co.,Ltd

D. Indications for use of the device:

It 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.

E. Device Description:

This Power wheelchair is a motor driven, indoor and outdoor transportation vehicle, which a device for assisting action handicapped people and disabled people to move. It is suitable for disabled people with mobility difficulties and elderly people.

The device consists of front wheel, drive wheel, frame, controller, motor, armrest, backrest, seat cushion, pedal, battery box and charger.

The device is powered by Li-ion Battery pack (24V 6Ah) with 10 Km range, which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet (100-240V, 50/60Hz) when the device is not in use.

The patient can activate the controller handle (joystick) to control the speed and direction of the wheelchair movement. In addition, when the patient releases the joystick, the joystick will return back to the central position and the wheelchair will be automatically stopped soon due to automatic electromagnetic brake system. Once the joystick is activated again move to other position, the wheelchair will be re-energized.

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 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 of brakes
- 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, 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 7176-16:2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices.
- 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

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K220747)	Remark
Common or Usual name	Power Wheelchair	Power Wheelchair	Same
Model(s)	BC-EA8000	N5515B	--
Indications for use	It 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.	It 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.	S.E.
Use condition	indoor and outdoor use	indoor and outdoor use	S.E
Number of wheels	4,including two front wheels and two rear Wheels	4,including two front wheels and two rear Wheels	S.E
Function of wheels	Front wheels:driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	Front wheels:driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	S.E
Movement control method	By Joystick control	By Joystick control	S.E
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	S.E
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E
Braking distance	⩽1.5 m	⩽1.5 m	S.E
Maximum safe	6°	9 °	Analysis

operational incline degree			
Armrest	PU	PU	S.E
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	S.E
Main frame material	Aluminum Alloy	Carbon fiber material	Analysis
Back cushion	Polyester fabric	Polyester fabric	S.E
Seat cushion	rubber patch cloth and Oxford fabric	rubber patch cloth and Oxford fabric	S.E
Overall Dimension (length*width*height)	950*625*930mm	940*610*960mm	Analysis
Folded Dimension (length*width*height)	775*440*410mm	720*310*610mm	Analysis
Front wheel size/type	5.9" x1.90" / PU Solid tire	7" x 1.75"/PU Solid tire	Analysis
Rear wheel size/type	10.6" x1.97" / PU Solid tire	8.5″x 2″/ PU Solid tire	Analysis
Max speed forward	Up to 6 km/h	Up to 6 km/h (1.6 m/s), adjustable	S.E
Max Speed backward	Less than 3 km/h (0.5 m/s)	Less than 3 km/h (0.5 m/s)	S.E
Max loading weight	100 Kg (≈220 lbs)	136kg (≈300 lbs)	Analysis
Battery	Lithium 24V6Ah	li-ion battery pack; rechargeable, 24 VDC 12Ah	S.E
Maximum distance of travel on the fully charged battery	10km	15 km	Analysis
Motor	Brushless DC motor; 24VDC; 150W, 2pcs	Brushless DC motor; 24VDC; 250W; 2pcs	S.E
Electronic controller	Brushless dual-drive rocker controller	Brushless dual-drive rocker controller	S.E
Turning Radius	900mm	900 mm	S.E
Maximum obstacle climbing	40 mm	40 mm	S.E

I. Difference analysis

The design and technological characteristics of the Power Wheelchair is similar to the predicates chosen. There are minor differences between the devices including Maximum safe operational incline degree, Main frame material, Overall Dimension,Folded Dimension, Rear wheel size/type, Max loading weight and Maximum distance of travel on the fully charged battery. All of the parameter with difference have been tested according to ISO7176 series standards and the test records support its safety and effectiveness. 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 Power Wheelchair (K220747).

The Power Wheelchair BC-EA8000 in its final finished form is identical to the Power Wheelchair (N5515B) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents)

Table 2 Safety comparison

Item	Proposed Device	Predicate Devices	Results
EMC	ISO7176-21	ISO7176-21	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Table 3 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 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	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 requirements of ISO 7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	S.E.
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.
ISO7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	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.

J. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, power wheelchair, BC-EA8000, is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K220747.