



October 29, 2024

JiaXing XiaoXiang Medical Equipment Technology Co., Ltd.
% Jarvis Wu
Senior Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
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China

Re: K241189

Trade/Device Name: Electric Wheelchair (ME23-EW16-BC200-01); Electric Wheelchair (ME23-EW16-BC200-02)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 15, 2024
Received: October 15, 2024

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 (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,

Heather L. Dean -S

Heather Dean, PhD
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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

Indications for Use

Submission Number (if known)

K241189

Device Name

Electric Wheelchair (ME23-EW16-BC200-01);
Electric Wheelchair (ME23-EW16-BC200-02)

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

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Prescription Use (Part 21 CFR 801 Subpart D)

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Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K241189

Document Prepared Date: 2024/4/28

A. Applicant:

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B. Device:

Trade Name: Electric Wheelchair

Common Name: Powered wheelchair

Models : ME23-EW16-BC200-01, ME23-EW16-BC200-02

Regulatory Information

Classification Name: Powered wheelchair

Classification: Class II

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device:

510(k) number: K220747

Classification Name: Powered wheelchair

Regulation Number: 890.3860

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 Electric Wheelchair, models: ME23-EW16-BC200-01,ME23-EW16-BC200-02, 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, seatbelt, pedal, battery box and charger.

The device is powered by Li-ion Battery pack with 22 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 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 Irritation And 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 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 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 7176-25:2022 Wheelchairs - Part 25: Lead-acid batteries and chargers for powered wheelchairs Requirements and test methods

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
Manufacturer	JiaXing XiaoXiang Medical Equipment Technology Co.,Ltd	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd	-
Common or Usual name	Power Wheelchair	Power Wheelchair	Same
Model(s)	ME23-EW16-BC200-01, ME23-EW16-BC200-02	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

JiaXing XiaoXiang Medical Equipment Technology Co.,Ltd
No.24-101,Lane 587,Taoyuan Road,Xiuzhou,Jiaxing,Zhejiang,China

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	≤ 1.9 m	≤ 1.5 m	Analysis
Maximum safe operational incline degree	10 °	9 °	S.E
Armrest	PUR (polyurethane)	PU	S.E
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 2.0A, Output: 29.4 Vdc, 2.8A;	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	S.E
Main frame material	Magnesium alloy	Carbon fiber material	Analysis
Back cushion	PUR (polyurethane)	Polyester fabric	Analysis
Seat cushion	PUR (polyurethane)	rubber patch cloth and Oxford fabric	Analysis
Overall Dimension (length*width*height)	1150*670*1030mm	940*610*960mm	S.E
Folded Dimension (length*width*height)	860*670*730mm	720*310*610mm	S.E
Front wheel size/type	7" x 2"/PU Solid tire	7" x 1.75"/PU Solid tire	S.E
Rear wheel size/type	10" x 2.5"/ PU solid tire	8.5 "x 2" / PU Solid tire	Analysis
Max speed forward	Up to 7.9 km/h (2.2 m/s), adjustable	Up to 6 km/h (1.6 m/s), adjustable	Analysis
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	125kg	136kg	Analysis

Battery	Li-ion battery pack; rechargeable, 25.6 VDC 16Ah	Li-ion battery pack; rechargeable, 24 VDC 12Ah	Analysis
Maximum distance of travel on the fully charged battery	22 km	15 km	Analysis
Motor	Brushless DC motor; 24VDC; 200W; 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	1100 mm	900 mm	Analysis
Maximum obstacle climbing	10 mm	40 mm	Analysis

Difference analysis:

The design and technological characteristics of the Electric Wheelchair is similar to the predicates chosen. There are minor differences between the devices including Braking distance, Main frame material, Back & Seat cushion, Rear wheel size, Max speed forward, Max loading weight, Maximum distance of travel on the fully charged battery, Battery, Turning Radius and Maximum obstacle climbing. 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).

Different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility tests are carried out according to ISO 10993 series.

Table 2 Safety comparison

Item	Proposed Device	Predicate Devices	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and ISO 10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	S.E.
EMC	ISO7176-21 & IEC 60601-2-1	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 7176-6	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 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.
	The test results shown that	The test results shown that	S.E.

ISO7176-15	information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	
ISO7176-16/ 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 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.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, Power Wheelchair, Models: ME23-EW16-BC200-01, E23-EW16-BC200-02, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K220747.