



November 12, 2024

Zhejiang Kairui Medical Device Co., Ltd.
% Xu Kiwi
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai, Shanghai 200122
China

Re: K242791
Trade/Device Name: Electric wheelchair (KR-8807)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 16, 2024
Received: September 16, 2024

Dear Xu Kiwi:

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
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K242791

Device Name

Electric wheelchair (KR-8807)

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)

☐ 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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Electric wheelchair (KR-8807)
Common Name	Powered wheelchair
Classification Name	Wheelchair, Powered
Regulation Number	890.3860
Product Code(s)	ITI

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K240913	Electric Wheelchair	ITI

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The subject device, Electric Wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick controller and adjusting speed. The Electric Wheelchair is a battery powered four wheeled vehicle. It consists Li-ion battery with an off-board battery charger, Push handle, Seat, Back support, Joystick controller, Control panel (including: Speed light, ON/OFF button, Horn, Joystick, Accelerated button, Deceleration button), Arm supports, Anti-tip wheel, Front wheel, Rear wheels.

The operation of the Controller: Use the On/Off button to turn on or turn off the power, The main function of the Joystick is to control the speed and direction of the wheelchair, the Joystick can control the wheelchair to travel in any direction, the operation of the Joystick movement will determine the wheelchair in that direction speed of movement. The farther the Joystick is moving from the center, the faster the wheelchair runs. When you release the Joystick, the wheelchair is automatically braked. Use the speed control button to

reduce or increase the speed setting. The Electric/ manual model change lever underneath the seat will allow for the brakes to engage or disengage. When adjusted to the manual model, the assistant can easily push the wheelchair. The Electric Wheelchair has a structure for quick assembly and disassembly that is convenient to be stored or placed in the trunk of your vehicle while traveling.

The Electric Wheelchair has 7 inch front wheels and 12 inch rear tires.

Max. distance of travel on the fully charged battery is 15 km and Max. speed forward is 6.5 km/h.

When the wheelchair needs to stop, release the joystick. After a set period of time, the controller disconnects the solenoid brake power supply, and the internal spring squeezes the suction plate and friction plate to lock the motor, so as to brake.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

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.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The design and technological characteristics of the Electric Wheelchair is similar to the predicate chosen. There are minor differences between the devices including Maximum safe operational incline degree, Armrest, Seat cushion, Rear wheel size/type, Max speed forward, Max loading weight, Battery, Maximum distance of travel on the fully charged battery, Turning Radius and Maximum obstacle climbing. All of the parameter with differences have been tested according to ISO 7176 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. Additionally, they do not influence the intended use of the device. Therefore, the proposed Wheelchair is substantially equivalent (SE) to The Power Wheelchair (K240913).

Different materials were used for parts in contact with user. These differences do not impact the safety and effectiveness of the subject device as demonstrated by biocompatibility tests carried out according to ISO 10993 series standards.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

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 maneuvering 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 7176-19:2022 Wheelchairs Part 19: Wheelchairs for use as seats in motor vehicles

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

The conclusion drawn from the nonclinical tests demonstrates that the subject device in the 510(K) submission, Electric Wheelchair,

Model KR-8807, is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K240913.