December 5, 2025

Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
Ariel Xiang
No.36 Danyan Road
Danyang, Jiangsu
China

Re: K252828
Trade/Device Name: Manual Wheelchair (Model W47)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: September 5, 2025
Received: September 5, 2025

Dear Ariel Xiang:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252828

Device Name
Manual Wheelchair (Model W47)

Indications for Use *(Describe)*
The W47 Manual Wheelchair is to provide mobility to persons limited to a sitting 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Prepared by 2025/12/2

Applicant Information:

Jiangsu Jumao X-Care Medical Equipment Co., Ltd.

Address: No.36 Danyan Road, Danyang City, Jiangsu, P.R. China

Device Name: Manual Wheelchair

Model: W47

Regulatory Information

Classification Name: Mechanical Wheelchair

Regulatory Class: I

Product code: IOR

Regulation Number: 890.3850

Review Panel: Physical Medicine

Device overview

A wheelchair is a chair with wheels, designed to be a replacement for walking, where it is propelled by the seated occupant turning the rear wheels by hand. There are also handles behind the seat for someone else to do the pushing. The device is intended for adults only (age ≥22 years).

W47 is a mechanical wheelchair including four wheels, a steel frame and a seat and back upholstery that is flame resistant. W47 has a physical dimension of 1340mm × 690mm × 950mm (overall length × overall width × handgrip height) with the seat itself has a dimension of 580mm × 450mm × 465mm (effective depth × width × seat height at front edge). The device has a weight capacity of 136 kilograms, and weighs about 24 kilograms. The armrest is non flip back/non height adjustable. Rear axle is offset axle, quick release axle. The device features hand brake levers on the rear push handles as well as wheel locks (parking brakes).

Indications for use

The W47 manual wheelchair is to provide mobility to persons limited to a sitting position.

Substantial Equivalence Information:

K170517

Merits Model R106/R136 Rehab Wheelchair

Merits Healthcare Industries (suzhou) Co., LTD.

1. Product Parameter

Table 1 General Comparison

	Proposed Device	**Primary predicate device**	**Comparison**
510k Number	---	K170517	------
Product Code	IOR	IOR	Same
Proprietary Name	Manual Wheelchair	Merits Model R106/R136 Rehab Wheelchair	------
Model	W47	R106, R136	------
Manufacturer	Jiangsu Jumao X-Care Medical Equipment Co., Ltd.	Merits Healthcare Industries. (suzhou) Co., LTD.	------

Indications for Use	The W47 manual wheelchair is to provide mobility to persons limited to a sitting position.	The Merits Model R106/R136 Rehab Wheelchair is to provide mobility to persons limited to a sitting position.	Same
Basic Design	W47 is a mechanical wheelchair including four wheels, a steel frame and a seat and back upholstery that is flame resistant.	The Merits Model R106/R136 Rehab Wheelchair are manual wheelchairs. They have adjustable headrest, adjustable armrests, cozy ergonomics seat and multiple axle position.	Same
Control Mode	Mechanical	Mechanical	Same
Physical Dimension	1340mm × 690mm × 950mm (length × width × handgrip height)	Model R106: 47.5” (±1”) × 28-32” (±1”) × 42” (±1”) i. e. 1026mm × 711mm ~ 813mm × 1067mm Model R136: 44.5” (±1”)	Similar The difference does not affect the effectiveness and safety.

		× 26-30” (±1”) × 42” (±1”) i.e. 1130mm × 660mm ~ 762mm × 1067mm	
Total Mass	24kg	Model R106: 89 lbs / 40.4kg Model R136: 62 lbs / 28.1kg	Similar The difference does not affect the effectiveness and safety.
Weight capacity	300lb (136kg)	300 lbs (136kg)	Same
Seat dimensions	580mm × 450mm × 465mm (effective depth × width × handgrip height)	Width:16-20”(406-508mm) Height: Model R106: 19-21”(483-533mm); Model R136: 21”(533mm) Depth: 18-20”(457-508mm)	Similar The difference does not affect the effectiveness and safety.
Armrest	Non flip back/Non height adjustable	Height Adjustable (8”~12”)	Similar The difference does not affect the effectiveness and safety.
Rear Wheel	606mm (23.9”)	Model R106: 610mm(24”)	Same

		Model R136: 317.5mm(12-1/2”)	
Casters	198mm (7.8”)	177.8mm (7”)	Similar The casters diameter of the subject device is larger than K170517. The difference does not affect the effectiveness and safety.
Headrest	Adjustable	Adjustable	Similar The difference does not affect the effectiveness and safety.
Wheel Lock	Pull to Lock	Pull to Lock	Same
Frame Materials	Steel	Steel	Same
Seat/Backrest /Arm Pad:	Polyurethanes (PU)	PU Foam	Same
Performance	Comply with： ISO7176-1	Comply with： ISO7176-1	Same

	ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO16840-10 ISO10993-1	ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO10993-1	

Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	The biocompatibility of the subject device is based on the use of low-biocompatibility-risk materials in accordance with Attachment G of FDA's 2023 Biocompatibility Guidance.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	S.E.
Performance	ISO 7176 -1/-3/-5/-7/-8/-11/-13/-15/-22, ISO 16840-10	ISO7176 -1/-3/-5/-7/-8/-11/-13/-15/-22, ISO 16840-10	S.E.

Label and labeling	Conforms to FDA Regulatory requirements	Conforms to FDA Regulatory requirements	S.E.

2. Substantial Equivalence Discussion

The proposed device and predicate device are complying to the same ISO standards, ISO 7176-1, ISO 7176-3, ISO 7176-5, ISO 7176-7, ISO 7176-8,, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-15, ISO 16840-10 and FDA guidance.

The proposed device performs in a similar manner to the predicate device. All these tests have corresponding requirements/ control criteria following above mentioned standards. And the test results show that the subject product is substantially equivalent to the predicate device in performance.

The performance testing demonstrates that the subject device is substantially equivalent to the predicate devices regarding Static ability (tipping angle), Dimension and weight, Dimension of wheel Static, impact and fatigue strengths, Dummy, friction of test surfaces, Documentation and labeling, Resistance to ignition.

The non-clinical laboratory data support the safety and performance of the subject device and demonstrate that the subject device should perform as intended in the specified use conditions.

3. Summary of non-clinical testing

The following performance data were provided to verify that the proposed device met all design specifications and provided support of the substantial equivalence determination.

ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability

ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes

ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering space

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 strength

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 7176-15:1996 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 7176-22：2014 Wheelchairs - Part 22: Set-up procedures

Biocompatibility of patient-contacting material

The biocompatibility of the subject device is based on the use of low-biocompatibility-risk materials in accordance with Attachment G of FDA’s 2023 Biocompatibility Guidance (“Use of International Standard ISO

10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’”).

4. Summary of clinical testing

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the manual wheelchair to its predicate device.

5. Substantial Equivalence Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, K170517 Merits Model R106/R136 Rehab Wheelchair.