December 5, 2025

Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
℅ Shouqiu Xiang
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K252825
Trade/Device Name: Manual Wheelchair (Model W45)
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 Shouqiu 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)*
K252825

Device Name
Manual Wheelchair (Model W45)

Indications for Use *(Describe)*
The W45 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared on 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: W45
Regulatory Information
Classification Name: Mechanical Wheelchair
Regulatory Class: I
Product code: IOR
Regulation Number: 890.3850
Review Panel: Physical Medicine

Substantial Equivalence Information:

Predicate Device: K181795
Manual Wheelchair
Sichuan AST Medical Equipment Co., Ltd.

Device Overview

The W45 Manual Wheelchair is a chair with wheels, designed to be a replacement for walking, where it is propelled by a caregiver using the rear push handles. The device is intended for adults only (age ≥22 years). W45 is a mechanical wheelchair including four wheels, features an aluminum frame, polypropylene hand grip and foot pedals, and a nylon upholstery that is flame resistant. W45 has a physical dimension of 1010mm × 610mm × 920mm (overall length × overall width × handgrip height) with the seat itself has a dimension of 470mm × 457mm × 449mm (effective depth× effective width × height at front edge). The device has a weight capacity of 115 kilograms, and weighs about 12 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, with a squeeze-locking mechanism that functions as a parking brake.

Indications for use

The W45 Manual Wheelchair is to provide mobility to persons limited to a sitting position.

1. Product Parameters

Table 1 General Comparison

Elements of Comparison	Subject Device (K252825)	Predicate Device (K181795)	Remark
Manufacturer	Jiangsu Jumao X Care Medical Equipment Co., Ltd.	Sichuan AST Medical Equipment Co., Ltd.	--
Common or Usual name	Manual Wheelchair	Manual Wheelchair	--
Classification	Class I	Class I	Same
Classification regulation	21 CFR 890.3850	21 CFR 890.3850	Same
Product code	IOR	IOR	Same
Indications for use	The W45 Manual Wheelchair is to provide mobility to persons limited to a sitting position.	It is to provide mobility to persons limited to a sitting position.	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Control Mode	Mechanical	Mechanical	Same
Model(s)	W45	MA012	--
Overall Dimensions (Length× Width× Height) (inch)	39.8×24×36.2 (1010mm*610mm* 920 mm)	46×25×35	Similar Minor difference on wheelchair dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Total weight	12kg	17.2kg/38lbs	Similar Different weight of the device do not raise the safety and effectiveness of the device.

Max loading weight	115kg (250lbs)	300lbs/136kg	Similar Difference on loading weight will not cause different performance. All safety and performance have been validated with the maximum loading weight.
Effective Seat width (inch)	18 (457mm)	16,18,20	Similar Minor difference on dimension of wheels will not cause different performance.
Seat height (inch)	17.7(449mm)	19.7	
Front wheel dimension (inch)	7.9 (200mm)	6,7,8	
Rear wheel dimension (inch)	12.2 (310mm)	20,22,24	
Frame type	foldable	foldable	Same
Back style	Fixed	Model MS019: Fixed Model MA012: Adjustable	Same
Wheel construction	Quick release	Quick release	Same
Armrest style	Fixed	Adjustable	Same
Main frame material	Aluminum	Aluminum	Same
Backrest, Seat cushion	Nylon	Nylon cushion	Same
Backrest style	Fixed	Adjustable	Similar The slight difference on back style do not raise the safety and effectiveness of the device.
Safety Feature	Hand brakes with locking position for parking	Manual Wheel Lock	Same
Performance	Comply with： ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11	Comply with： ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11	Same

	ISO7176-13 ISO7176-15 ISO16840-10 ISO10993-1	ISO7176-13 ISO7176-15 ISO7176-16 ISO10993-1	

Table 2 safety comparison

Item	Subject 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	ISO 7176 -1/-3/-5/-7/-8/-11/-13/-15/-22, 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 tissue-contacting materials

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. Substantial Equivalence Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, K181795 Manual Wheelchair from Sichuan AST Medical Equipment Co., Ltd.