January 29, 2026

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

Re: K253632
Trade/Device Name: Manual Wheelchair (W50)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: January 26, 2026
Received: January 26, 2026

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,

Digitally signed by
MARY S. KESZLER -S
Date: 2026.01.29
14:19:00 -05'00'

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253632

Please provide the device trade name(s).

Manual Wheelchair (W50)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253632

510(k) Summary

Prepared on: 2026-01-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
Applicant Address	No.36 Danyan Road, Danyang City, Jiangsu, P.R. China Danyang Jiangsu, China
Applicant Contact Telephone	+86 16605112488
Applicant Contact	Mr. Weixia Shi
Applicant Contact Email	ly.sys01@jumaocn.cn
Correspondent Name	Shanghai SUNGO Management Consulting Co., Ltd.
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Correspondent Contact Telephone	+86-21-58817802
Correspondent Contact	shouqiu Xiang
Correspondent Contact Email	shouqiu.xiang@sungoglobal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Manual Wheelchair (W50)
Common Name	Mechanical wheelchair
Classification Name	Wheelchair, Mechanical
Regulation Number	890.3850
Product Code(s)	IOR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181795	Manual Wheelchair	IOR

Device Description Summary

21 CFR 807.92(a)(4)

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. W50 is a mechanical wheelchair including four wheels, a steel frame cover black paint and a textilene upholstery that is flame resistant. W50 has a physical dimension of 1130mm × 840mm × 950mm (depth × width × height) with the seat itself has a dimension of 525mm ×590mm × 470mm (depth × width × height). The device has a weight capacity of 227 kilograms, and weighs about 24 kilograms. The color is dark black.

Occupant mass group of the manual wheelchair belongs to III. Armrest is non flip back/non height adjustable. Rear axle is offset axle, quick release axle.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

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

Technological Comparison

21 CFR 807.92(a)(6)

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.

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:
 ISO10993-5:2009 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity
 ISO10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
 ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
 ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
From the test result, we can find the material are safety and can meet the requirements.

 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

N/A

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.
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.