June 14, 2021

Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
% Jinghua Zhou
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, Guangdong 511660
China

Re: K200466
Trade/Device Name: Manual Wheelchair (Model W28)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Received: May 19, 2021

Dear Jinghua Zhou:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Dean, PhD
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K200466

Device Name
Manual Wheelchair (Model W28)

Indications for Use *(Describe)*
The W28 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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# Section 5 - 510(k) Summary

Date of Summary Preparation: Feb 17, 2020
Date of Summary modification: May 6, 2021

### 1. Submitter's Identifications

Submitter's Name: Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
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### 2. Correspondent's Identifications

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### 3. Name of the Device

Device Classification Name: Wheelchair, Mechanical
Common Name: Mechanical Wheelchair
Trade Name: Manual Wheelchair
Model: W28
Classification Panel: Physical Medicine
Product Code: IOR
Device Classification: Class I

### 4. The Predicate Devices

K170517 Merits Model R106/R136 Rehab Wheelchair

### 5. Device Description

A mechanical 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. Wheelchairs are used by people for whom walking is difficult or impossible due to illness, injury, or disability. The device is intended for adults only.

W28 is a mechanical wheelchair including four wheels, a steel frame cover black paint and a textilene upholstery that is flame resistant. W28 has a physical dimension of 1100mm × 670mm × 908mm (depth × width × height) with the seat itself has a dimension of 415mm × 500mm × 475mm (depth × width × height). The device has a weight capacity of 136 kilograms, and weighs about 20.5 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.

The components include frame, back upholstery, seat upholstery, handgrip, armrest, armrest pad, side panel,

rear wheel, handrim, wheel lock, caster, caster fork, footrest, footplate.

Main materials: Steel (frame, armrest, wheel lock, caster fork, footrest, footplate), PVC (handgrip, side panel, handrim, caster, back upholstery, seat upholstery, armrest pad, rear wheel)

**6. Indication for Use / Intended Use of Device**

The W28 Manual Wheelchair is to provide mobility to persons limited to a sitting position.

**7. Summary of Substantial Equivalence**

**Table 1 Comparison to Predicate Device**

| | **Proposed Device** | **Primary predicate device** |
|---|---|---|
| **510k Number** | K200466 | K170517 |
| **Product Code** | IOR | IOR |
| **Proprietary Name** | Manual Wheelchair | Merits Model R106/R136 Rehab Wheelchair |
| **Model** | W28 | R106/R136 |
| **Manufacturer** | Jiangsu Jumao X-Care Medical Equipment Co., Ltd. | Merits Healthcare Industries. (suzhou) Co., LTD. |
| **Indications for Use** | The W28 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. |
| **Basic Design** | W28 is a mechanical wheelchair including four wheels, a steel frame cover black paint and a textilene 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. |
| **Materials** | Steel (frame, armrest, wheel lock, caster fork, footrest, footplate), PVC (handgrip, side panel, handrim, caster, back upholstery, seat upholstery, armrest pad, rear wheel) | Frame Material: Steel<br>Seat/Backrest Pad: Cozy Ergonomics PU Foam |
| **Components** | Frame, back upholstery, seat upholstery, handgrip, armrest, armrest pad, side panel, rear wheel, handrim, wheel lock, caster, caster fork, footrest, footplate. | Not publicly available |
| **Occupant mass group** | III | III |

| | | |
|---|---|---|
| **Control Mode** | Mechanical | Mechanical |
| **Physical Dimension** | 1100mm × 670mm × 908mm (depth × width × height) | Model R106: 47.5” (±1”) × 28-32” (±1”) × 42” (±1”)<br>i.e. 1206mm × 711mm ～ 813mm × 1067mm<br>Model R136: 44.5” (±1”) × 26-30” (±1”) × 42” (±1”)<br>i.e. 1130mm × 660mm ～ 762mm × 1067mm |
| **Total Mass** | 20.5 kg | Model R106: Not publicly available<br>Model R136: Not publicly available |
| **Weight capacity** | 300lb (136kg) | 300lb (136kg) |
| **Seat dimension** | 415mm × 500mm × 475mm (depth × width × height) | Width:16-20”(406-508mm)<br>Height: Model R106: 19-21”(483-533mm); Model R136: 21”(533mm)<br>Depth: 18-20”(457-508mm) |
| **Armrest** | Not flip back/Not height adjustable | Height Adjustable (8”~12”) |
| **Rear Axle** | Offset axle, Quick release axle | Model R106: Multiple<br>Model R136: Fixed |
| **Real Wheel** | 610mm(24”) | Model R106: 610mm(24”)<br>Model R136: 317.5mm(12-1/2”) |
| **Casters** | 203mm(8”) | 177.8mm (7”) |
| **Headrest** | Not adjustable | Adjustable |
| **Backrest Angle** | 16.9° | 9°~57° |
| **Seat Plane Angle** | 4° | 4°~34° |
| **Elevating Legrest** | Standard | Standard |
| **Turning Radius** | Required width of angled corridor: 950mm; Required doorway entry depth: 1650mm; Required corridor width for side opening: 1050mm | Model R106:30”~35.8”(76.5cm~91cm)<br>Model R136:32”~38.1”(81.5cm~96.8cm) |
| **Shear Reduction** | Aligned Backrest Recline & User Pivot Points | Aligned Backrest Recline & User Pivot Points |
| **Wheel Lock** | Pull to Lock | Not publicly available |

| | | |
|---|---|---|
| **Frame Construction** | Foldable Frame | Fixed Frame (Not foldable) |
| **Color** | Black | Not publicly available |
| **Standard** | ISO7176-1<br>ISO7176-3<br>ISO7176-5<br>ISO7176-7<br>ISO7176-8<br>ISO7176-11<br>ISO7176-13<br>ISO7176-15<br>ISO7176-16<br>ISO10993-1<br>ISO10993-5<br>ISO10993-10 | ISO7176-1<br>ISO7176-3<br>ISO7176-5<br>ISO7176-7<br>ISO7176-8<br>ISO7176-11<br>ISO7176-13<br>ISO7176-15<br>ISO7176-16<br>ISO10993-1<br>ISO10993-5<br>ISO10993-10 |

**8. Substantial Equivalence discussion:**

Our device and the predicate device are almost identical in terms of all areas described in the above table (*Table 1*). Most main substantial equivalences are: basic design, weight capacity (300bls), frame material (steel), and the basic descriptions for intended use of the three devices are the same. There are some minor differences with the predicate device not affect the safety or effectiveness of the subject device. These minor differences are: material of back upholstery and seat upholstery, physical dimension, armrest (not flip back/not height adjustable), seat dimension, casters dimension, headrest (not adjustable), backrest angle, seat plane angle, turning radius, frame construction (foldable). Proposed device compare to predicate device, even with these slight differences, have been shown to be safe and effective through type testing, internal performance testing, biocompatibility evaluation and usability studies.

The following table (*Table 2*) shows similarities and differences of the performance between our device and the predicate device. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for Mechanical Wheelchair, model W28 met all relevant requirements in the test standards, our internal specifications, and are comparable to the predicate device.

**Table 2: Comparison of Performance Testing**

| Description | Proposed Device | Predicate device |
|---|---|---|
| Static stability | Meets ISO 7176-1:2014 | Meets ISO 7176-1:2014 |
| Effectiveness of brakes | Meets ISO 7176-3:2012 | Meets ISO 7176-3:2012 |
| Dimensions, mass and manoeuvring space | Meets ISO 7176-5:2008 | Meets ISO 7176-5:2008 |
| Seating and wheel dimensions | Meets ISO 7176-7:1998 | Meets ISO 7176-7:1998 |
| Static, impact, and fatigue strengths | Meets ISO 7176-8:2014 | Meets ISO 7176-8:2014 |
| Information disclosure, documentation and Labeling | Meets ISO 7176-15:1996 | Meets ISO 7176-15:1996 |
| Resistance to ignition | Meets ISO 7176-16:2012 | Meets ISO 7176-16:2012 |

The tests were performed following the general requirements outlined in ISO 7176-11:2012, ISO 7176-13:1989.

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Proposed Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Mechanical Wheelchair model W28 meets performance requirements per ISO 7176-1:2014, ISO 7176-3: 2012, ISO 7176-5:2008, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-11:2012, ISO 7176-13: 1989, ISO 7176-15: 1996, and ISO 7176-16:2012. It is safe and effective, and its performances meet the requirements of the pre-defined acceptance criteria and intended use.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for manual wheelchair cleared by the 510(k) process.

According to the non-clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

**9. Non-Clinical Tests Performed:**

The following testing was performed on the "Mechanical Wheelchair" model W28 in accordance with the requirements of the design control regulations and established quality assurance procedures.

Safety and performance:
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 manoeuvring 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 strengths
ISO 7176-11:2012 Wheelchairs – Part 11: Test dummies
ISO 7176-13:1989 Wheelchairs – Part 13: Determination of friction of test surface
ISO 7176-15:1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labeling
ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices

Biocompatibility:
ISO 10993-1:2009/C1:2010 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity

**10. Biocompatibility**

Type of contact: Skin contact duration category A < 24 hours.
Patient contact: Contact of intact skin of hands, arms, back, neck and thigh with the following materials:
Handgrip: made up of PVC, contacts with intact skin of hands of user and/or caregiver.
Side panel: made up of PVC, contacts with intact skin of thighs of user.
Seat upholstery and back upholstery: the cover material is made up of leatherette, inner cover material is made up of plastics, both are actually polyvinyl chloride, referred to as PVC. They contact with intact skin of back, neck and thigh of user.
Armrest pad: made up of PVC, contacts with intact skin of hands and arms of user.
Handrim: made up of PVC, contacts with intact skin of hands and arms of user.
Because handgrip, side panel, seat upholstery, back upholstery, armrest pad and handrim are all composed of the same PVC with additives, we chose handgrip as the test sample. Handgrip included PVC with additives was performed test together. The materials only contact with the user's intact skin within 24 hours, so according to ISO 10993-1:2009, the In Vitro Cytotoxicity Test, Skin Sensitization Test and Skin

Irritation Test have been performed.
The Manual Wheelchair, model W28 uses the similar contacting materials as the predicate device and does not raise any new biocompatibility issues.

**11. Conclusion:**

Based on the comparison of the proposed device of W28 is determined to be Substantially Equivalent (SE) to the predicate device of Merits Model R106/R136 Rehab Wheelchair, in respect of safety and effectiveness.