September 15, 2023

Zhenjiang Assure Medical Equipment Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K232198
Trade/Device Name: Reclining wheelchair (YJ-011S 16"D, YJ-011S 16"DF, YJ-011S 18"D, YJ-011S 18"DF, YJ-011S 20"D, YJ-011S 20"DF)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: July 25, 2023
Received: July 25, 2023

Dear Eva Li:

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,

Tushar Bansal -S

for 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

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)*
K232198

Device Name
Reclining wheelchair (YJ-011S 16”D, YJ-011S 16”DF, YJ-011S 18”D, YJ-011S 18”DF, YJ-011S 20”D, YJ-011S 20”DF)

Indications for Use *(Describe)*
The YJ-011S 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.

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510(k) Summary

K232198

1. Submitter

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Room 1401, Dongfang Building, 1500# Century Ave, Shanghai, 200122 CHN

Prepared Date: July 18th,2023

2. Device

Name of Device: Reclining wheelchair
Common Name: Manual Wheelchair
Model(s): YJ-011S 16”D, YJ-011S 16”DF, YJ-011S 18”D, YJ-011S 18”DF, YJ-011S 20”D, YJ-011S 20”DF

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

3. Predicate device:

K201461
Ningbo Shenyu Medical Equipment Co.,Ltd.
Manual Wheelchair (A011)

4. Device description

The YJ-011S series is a mechanical wheelchair which is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It can be folded for transport by bringing the two sides together. The manual wheelchair incorporates a main frame, a seat, two adjustable footrests and four wheels.

The larger rear wheels have hand rims of slightly smaller diameter projecting just beyond the tire. These allows the user to maneuver the chair by pushing them on without requiring them to grasp the tires. The manual wheelchairs have brakes that bear on the tires of the rear wheels and two push handles at the upper rear of the frame to allow for manual propulsion by an assistant.

Main Components:

Main frame, back upholstery, seat upholstery, handgrip, armrest, front wheel, rear wheel, hand rim, crossbar, footplates, brake, leg rest.

The device can be operated indoors, or outdoors on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The specification table is as below:

Model	YJ-011S 16”D, YJ-011S 16”DF, YJ-011S 18”D, YJ-011S 18”DF, YJ-011S 20”D, YJ-011S 20”DF		
Overall dimension	length 1340mm* high 1258mm *16"width 625mm *18"width 675mm *20"width 725mm		
Folded dimension	width 323mm		
Seat width	16" 410mm 18" 460mm 20" 510mm	Seat plane angle	3°
Seat depth	460mm	Seat height from floor	525mm
Backrest angle	7°-83.5°	Backrest height	500mm
Backrest width	16" 410mm 18" 460mm 20" 510mm	Footrest-to-seat distance	448mm-555mm
Footrest clearance	72mm	Footrest length	200mm
Armrest-to-seat distance	228mm	Footrest-leg-angle	95°
Leg-to-seat-surface angle	140°	Front-armrest-to-backrest distance	**-D:** 320mm -**F:** 475mm
Front-armrest-to-backrest distance	**-D**: 320mm **-F**: 475mm	Armrest length	**-D**: 260mm **-F**: 352mm
Armrest width	55mm	Armrest angle	3°-4°
Distance between armrests	16" 427mm 18" 477mm 20" 527mm	Front location of armrest structure	320mm
Hand rim diameter	Φ580mm	Material	Q235
Horizontal location of axle	55°	Maximum weight bearing capacity of the device	350LBS
Weight of the device(net)	25.5kg	Static stability sideways	15.25°
diameter of front wheels	Φ195mm	diameter of rear wheels	Φ613mm
Static stability uphill	15.2°	Static stability downhill	15.2°
Minimum turning radius		1170mm	

Parking brake	
Max slope uphill	8.35°
Max slope downhill	8.15°

5. Indication for use

The YJ-011S Manual Wheelchair is to provide mobility to persons limited to a sitting position.

6. Comparison of technological characteristics with the predicate device

Device	Predicate Device	Proposed Device	Results
510K Number	K201461	K232198	——
Manufacturer	Ningbo Shenyu Medical Equipment Co., Ltd.	Zhenjiang Assure Medical Equipment Co., Ltd.	——
Proprietary Name	Manual Wheelchair	Reclining wheelchair	——
Classification	I	I	same
Indications for use	The A011 Manual wheelchair is to provide mobility to persons limited to a sitting position.	The YJ-011S reclining wheelchair is to provide mobility to persons limited to a sitting position.	same
Design Characteristic	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull-to-Lock, Armrest, Backrest, Foot rest	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull-to-Lock, Armrest, Backrest, Foot rest, skirt guard	Similar*1
Brake control	occupant-operated brake only	occupant-operated brake only	same
Operation Environment	For indoor/outdoor use	For indoor/outdoor use	same
Control Mode	Mechanical	Mechanical	same
Size(unfold)	1100 (L) *660 (W) * 910mm (H)	1340 (L)* 1258 (H) *16" 625mm(W) *18" 675mm(W) *20" 725mm(W)	Different*2
Stowage length/width/height	810 (L) X 320 (W) X 930mm (H)	1340 (L)* 1258 (H)*323mm(W)	different*2
Weight (Total)	16kg(35.2lbs)	25.5kg	different*2
Weight Capacity	136Kg(300lbs)	350LBS	different*2
Seat Width	480mm	410-510mm	different*2
Seat height	540mm	525mm	different*2
Seat depth	420mm	460mm	different*2
Back type	Fixed	Adjustable	Different*3
Tires	Front: 200mm Rear:610mm	Front: 195mm Rear:613mm	different*2
Armrest	Flip back armrest	fixed	different*3
Foot rest	Optional/ swing away Optional/ swing away	Optional/ swing away Optional/ swing away	same

Rear Axle Position	Single	Single	Same
Frame Construction	Foldable frame Push inward from left and right sides to fold	Foldable frame Push inward from left and right sides to fold	Same
Safety Feature	Manual Wheel Lock	Manual Wheel Lock	Same
Performance	Comply with： ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16	Comply with： ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16	Same
Biocompatibility	Comply with： ISO10993-1 ISO10993-5 ISO10993-10	Comply with： ISO10993-5 ISO10993-10 ISO10993-23	Similar*4

Discussion：

Similar*1:	Compared to the predicate device, the subject device adds two skirt guards which installed to the sides of the seat frame under the arm rests to provide a barrier between the occupant and the wheels. This feature can prevent occupant's clothes from getting caught in the wheels. This feature will not raise any new risk of safety or effectiveness.
Different*2:	Compared to the predicate device, the subject device has different value on the unfold size, stowage size, device weight, capacity, seat width, seat height, seat depth, tire size. However, the subject has passed the <ISO 7176-7-1998 Part7: Measurement of seating and wheel dimensions > and <ISO 7176-5-2008 Part 5: Determination of dimensions, mass and maneuvering space>, so the above different will not raise any new risk of safety or effectiveness.
Different*3:	Compared to the predicate device, the subject device's back is adjustable, and the arm can't be flipped. These differences will not raise any new risk of safety or effectiveness.
Similar*4	The stimulation test in ISO 10993-23 replaces the stimulation test in ISO 10993-10:2010. It will not raise any new risk of safety or effectiveness.

7. Summary of Non-Clinic Performance Testing

Performance Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications and 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 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes

ISO 7176-5: 2008 Wheelchairs - Part 5: Determination of overall 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 strengths
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 7176-16:2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices
ISO 7176-22:2014 Wheelchairs — Part 22: Set-up procedures

Biocompatibility

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process."* Testing included:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-23:2021)

The testing supports the biocompatibility of the patient-contacting device materials that were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission is as safe and effective as the legally marketed predicate device cleared under K201461.