October 3, 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: K232230
Trade/Device Name: YJ-K1/K2 Wheelchair (YJ-K1F 16" NDE; YJ-K1F 16" NDS; YJ-K1F 18" NDE; YJ-K1F 18" NDS; YJ-K1F 20" NDE; YJ-K1F 20" NDS; YJ-K1F 18" NDEE; YJ-K1F 16" VDE; YJ-K1F 16" VDS; YJ-K1F 18" VDE; YJ-K1F 18" VDS; YJ-K1F 20" VDE; YJ-K1F 20" VDS; YJ-K2 16" VDFE; YJ-K2 16" VDFS; YJ-K2 18" VDFE; YJ-K2 18" VDFS; YJ-K2 20" VDFE; YJ-K2 20" VDFS; YJ-K1G 18" NFFE; YJ-K1G 18" NFFS; YJ-K2TC 16" NAFE; YJ-K2TC 18" NAFE; YJ-K2TC 20" NAFE)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: July 27, 2023
Received: July 27, 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 (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.

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

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.

Submission Number *(if known)*

K232230

Device Name

YJ-K1/K2 Wheelchair (YJ-K1F 16" NDE; YJ-K1F 16" NDS; YJ-K1F 18" NDE; YJ-K1F 18" NDS; YJ-K1F 20" NDE; YJ-K1F 20" NDS; YJ-K1F 18" NDEE; YJ-K1F 16" VDE; YJ-K1F 16" VDS; YJ-K1F 18" VDE; YJ-K1F 18" VDS; YJ-K1F 20" VDE; YJ-K1F 20" VDS; YJ-K2 16" VDFE; YJ-K2 16" VDFS; YJ-K2 18" VDFE; YJ-K2 18" VDFS; YJ-K2 20" VDFE; YJ-K2 20" VDFS; YJ-K1G 18" NFFE; YJ-K1G 18" NFFS; YJ-K2TC 16" NAFE; YJ-K2TC 18" NAFE; YJ-K2TC 20" NAFE)

Indications for Use *(Describe)*

The YJ-K1/K2 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

1. Submitter

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Prepared Date: Oct 1st ,2023

2. Device

Name of Device: YJ-K1/K2 Wheelchair
Common Name: Manual Wheelchair
Model(s):

YJ-K1F 16" NDE	YJ-K1F 16" NDS	YJ-K1F 18" NDE	YJ-K1F 18" NDS	YJ-K1F 20" NDE	YJ-K1F 20" NDS
YJ-K1F 18" NDEE	YJ-K1F 16" VDE	YJ-K1F 16" VDS	YJ-K1F 18" VDE	YJ-K1F 18" VDS	YJ-K1F 20" VDE
YJ-K1F 20" VDS	YJ-K2 16" VDFE	YJ-K2 16" VDFS	YJ-K2 18" VDFE	YJ-K2 18" VDFS	YJ-K2 20" VDFE
YJ-K2 20" VDFS	YJ-K1G 18" NFFE	YJ-K1G 18" NFFS	YJ-K2TC 16" NAFE	YJ-K2TC 18" NAFE	YJ-K2TC 20" NAFE

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)
This predicate has not been subject to a design-related recall.

4. Device description

The YJ- K1,K2 series are mechanical wheelchairs which are a manually operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position. It can be folded for transport by bring 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 manoeuvre 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, Anti-tipper (selected models), brake extender(selected models).

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

5. Indication for use

The YJ-K1/K2 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	K232230	——
Manufacturer	Ningbo Shenyu Medical Equipment Co., Ltd.	Zhenjiang Assure Medical Equipment Co., Ltd.	——
Proprietary Name	Manual Wheelchair	YJ-K1/K2 Wheelchair	——
Model	A011	24 models	——
Classification	I	I	same
Indications for use	The A011 Manual wheelchair is to provide mobility to persons limited to a sitting position.	The YJ-K1/K2 Manual 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， Anti-tipper (selected models), brake extender(selected models)	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)	1220 (L) *660/640/700 (W) * 857/908mm (H)	Different*2

Stowage length/width/height	810 (L) X 320 (W) X 930mm (H)	1220(L)*280/285/310(W)*857/908mm(H)	different*2
Weight(Total)	16kg(35.2lbs)	20.0kg/22.6kg	different*2
Weight Capacity	136Kg(300lbs)	136Kg(300lbs)	same
Seat Width	480mm	405/455/505mm	different*2
Seat height	540mm	490mm/445mm	different*2
Seat depth	420mm	16'',18'',20''	different*2
Back type	Fixed	Fixed	same
Tires	Front: 200mm Rear:610mm	Front: 193mm Rear:610mm	different*2
Armrest	Flip back armrest	Fixed/flip up	different*3
Foot rest	Optional/ swing away Optional/ swing away	swing away footrest/ elevating leg rest	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
Safe Operational incline	Vertical forward tilt ≥10°, vertical backward tilt ≥10°, and lateral tilt ≥15°	Vertical forward tilt ≥10°, vertical backward tilt ≥10°, and lateral tilt ≥10°	Similar*2
braking time	The manual wheelchair brake is mechanical structure and manual braking, and the braking time can be ignored when it is used immediately.	The manual wheelchair brake is mechanical structure and manual braking, and the braking time can be ignored when it is used immediately.	Same
braking distance	N/A	brake is mechanical structure and manual braking, and the braking distance can be ignored.	Similar*2
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： ISO10993-1 ISO10993-5 ISO10993-10	Same

Disscussion：

Similar*1:	Compare the predicate device, the subject device add two skirt guards which installed to the sides of the seat frame under the arm rests to provide a barrier between the occupants and the wheels. This feature can prevent occupant s' clothes from getting caught in the wheels. And the subject device equipped Anti-tipper (selected models), brake extender(selected models). This feature will not raise any new risk of safety or effectiveness.
Different*2:	Compare the predicate device, the subject device have different value on the unfold size, stowage size, device weight, Capacity, Seat Width, Seat height, Seat depth, Tires size. However the subject has pass the <ISO 7176-7-1998 Part7: Measurement of seating and wheel dimensions > and <ISO 7176-5-2008 Part 5: Determination of dimensions, mass and manoeuvring space>, so the above different will not raise any new risk of safety or effectiveness.
Different*3:	Compare the predicate device, the subject device armrest have various options. These difference will bot raise any new risk of safety or effectiveness.
Similar*2	The Safe Operational incline is not identical, the subject device pass the bench performance. So it will bot 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 as 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 10993-10:2010)

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 510(K) submission, the subject device is as safe, as effective, as the legally marketed predicate device cleared under K201461.