June 5, 2023

Zhenjiang Assure Medical Equipment Co.,Ltd.
Eric Shi
QA & QC Manager
No.297, Chuqiao road,
Zhenjiang city, Jiangsu province
China

Re: K231320
Trade/Device Name: Zhenjiang Assure Mechanical Wheelchair, Model:K1
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: May 5, 2023
Received: May 8, 2023

Dear Eric Shi:

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

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

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)*
K231320

Device Name
Zhenjiang Assure Mechanical Wheelchair,model:K1

Indications for Use *(Describe)*
The device is intended for medical purpose to provide mobility to persons restricted 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

510k Summary

As per 21 CFR 807.92

1.Submitter Information

Company Name:Zhenjiang Assure Medical Equipment Co.,Ltd.

Address: No.297, Chuqiao road, Zhenjiang city, Jiangsu province,China.

Phone:+86-18621771627

Contact Person (including title):Eric Shi (QA&QC Manager)

E-mail:eric-shi@isosh.com

Subject Device Information

- Type of 510(k) submission:Special
- Common Name:Mechanical Wheelchair
- Proprietary Name:Zhenjiang Assure Mechanical Wheelchair,model:K1
- Regulation Name:Wheelchair, Mechanical
- Product Code:IOR
- Regulation Number:890.3850
- Regulation Class:1

2.Predicate Device Information

- Sponsor:Zhenjiang Assure Medical Equipment Co., Ltd
- Common Name: Mechanical Wheelchair
- Proprietary Name:Zhenjiang Assure Mechanical Wheelchair, model:A227
- Regulation Name:Wheelchair, Mechanical
- 510(k) number:K112816
- Product Code:IOR
- Regulation Number:890.3850
- Regulation Class:1

3.Device Description

The Zhenjiang Assure Mechanical Wheelchair,model:K1 is indoor/outdoor wheelchair that has a base with four-wheeled with a seat.The device can be disassembled for transport and it is foldable easily.The device can be disassembled for transport and it is foldable easily.The device is

consistent with the ISO 7176 series standards and uses a standard sling type back and seat, the upholstery fabric meets the flame retardant test.

4.Summary of Comparison and Technological Characteristics

Elements of Comparison	Subject Device: K231320	Predicate Device: K112816	Comment
Proprietary Name	Zhenjiang Assure Mechanical Wheelchair,model:K1	Zhenjiang Assure Mechanical Wheelchair, model:A227	N/A
General Comparison			
510(k) Number	K231320	K112816	N/A
Regulation Name	Wheelchair, Mechanical	Wheelchair, Mechanical	Same
Regulation Number	890.3850	890.3850	Same
Product Code	IOR	IOR	Same
Indications for Use	The device is intended for medical purpose to provide mobility to persons restricted to a sitting position.	The device is intended for medical purpose to provide mobility to persons restricted to a sitting position.	Same
Model	K1	A227	
Over-The-Counter Use	Yes	Yes	
Where used	Indoor/outdoor	Indoor/outdoor	Same
Target population	The elderly and disabled	The elderly and disabled	Same
Frame Material	high-quality SPCC steel pipe	high-quality SPCC steel pipe	Same
Framework	foldable	foldable	Same
Casters	8”	5” ~ 8”	Note 1
Rear wheel	24”	12 1/2” ~ 22”	
Seat length	16”~18”	10~17”	
Seat height	19.5”	21”	

Elements of Comparison	Subject Device	Predicate Device	Comment
Seat width	16”~20”	10”~18”	
Max loading	136 kg/300 lbs	100 kg/220 lbs	
Materials	high-quality SPCC steel pipe	high-quality SPCC steel pipe	Same
Components of Mechanical Wheelchair	Handle Footplate Backrest Armrest Front caster Front fork Rear wheel	Handle Footplate Backrest Armrest Front caster Front fork Rear wheel	Note 2
Handle size	103*34mm	103*34mm	Same
Footplate size	197*161mm	197*161mm	Same
Backrest size	16”~20”	16”~20”	Same
Armrest size	10.12” x 2.2” x 1.42”	10.12” x 2.2” x 1.42”	Same
Front caster size	8”*1.25”	8”*1”	Same
Rear wheel size	24”*1”	24”*1”	Same
Handle size	103*34mm	103*34mm	Same
Performance	compatible as requirement of ISO7176-1:1999,ISO7176-3:2003,ISO7176-5:2008,ISO7176-11:1992,ISO7176-13:1989,ISO7176-15:1996,ISO7176-16:1997	compatible as requirement of ISO7176-1:1999,ISO7176-3:2003,ISO7176-5:2008,ISO7176-11:1992,ISO7176-13:1989,ISO7176-15:1996,ISO7176-16:1997	Same

Note 1: The K1 is a new specification for predicate device.The parameters of Casters,Rear wheel,Seat length,Seat height,Seat width and Max loading differ from those of predicate devices.

Note 2: The K1 is a new specification for predicate device.The K1 is also composed of Handle,Footplate,Backrest,Armrest,Front caster,Front fork and Rear wheel.The design of front fork is differ from those of predicate devices.

6.Summary of Verification and Validation

The manufacturer has performed non-clinical performance testing based on its risk assessment utilizing Failure Mode Effect Analysis (FMEA).

Following Quality System processes,required testing was conducted to validate the cumulative modifications made to the subject devices.

Performance test

No.	FDA recognition number	Standards Development Organization (SDO), Designation Number-Year, and Title
1	16-195	ISO 7176-1:2014 Wheelchairs-Part 1: Determination of static stability.
2	16-192	ISO 7176-3:2012 Wheelchairs-Part 3: Determination of effectiveness of brakes
3	16-163	ISO 7176-5:2008 Wheelchairs-Part 5:Determination of overall dimensions, mass and maneuvering space
4	16-190	ISO 7176-11:2012 Wheelchairs-Part 11: Test dummies
5	16-25	ISO 7176-13:1989 Wheelchairs-Part 13:Determination of coefficient of friction of test surfaces
6	16-27	ISO 7176-15:1996 Wheelchairs-Part 15:Requirements for information disclosure, documentation and labelling.
7	16-191	ISO 7176-16:2012 Wheelchairs-Part 16:Resistance to ignition of upholstered parts, Requirements and test methods

7.Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate device

8.Prepared Date

6 May 2023