March 31, 2026

Zhenjiang Assure Medical Equipment Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd
Rm. 1401, Dongfang Bldg., 1500# Century Ave.
Shanghai, 200122 CHN

Re: K260319
Trade/Device Name: K5 wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: January 30, 2026
Received: January 30, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.03.31 11:23:50 -04'00'

for Tushar Bansal, PhD
Acting Assistant Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260319

Device Name
K5 wheelchair

Indications for Use *(Describe)*
The K5 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.

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

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1. Submitter

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Prepared Date: March 31, 2026

2. Device

Name of Device: K5 wheelchair
Common Name: Manual Wheelchair
Model(s):
16” with swing-away footrest
18” with swing-away footrest
20” with swing-away footrest
16” with elevated foot rest(ELR)
18” with elevated foot rest(ELR)
20” with elevated foot rest(ELR)

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

3. Predicate device:

K232198
Zhenjiang Assure Medical Equipment Co., Ltd.
Reclining wheelchair
This predicate has not been subject to a design-related recall.

4. Device description

The K5 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 bring the two sides together. The manual wheelchair incorporates a main frame, a seat, two adjustable footrests,2 removable foot

rests 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.

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	16” with swing-away footrest 18” with swing-away footrest 20” with swing-away footrest 16” with elevated foot rest(ELR) 18” with elevated foot rest(ELR) 20” with elevated foot rest(ELR)		
Overall dimension	length 1850mm* high 960-1040mm *16" 625mm(W) *18" 675mm(W) *20" 725mm(W)		
Folded dimension	1850*960*460mm(L*H*W)		
Seat width	405mm	Seat plane angle	3.5°
Seat depth	400mm	Seat height from floor	520mm
Backrest angle	15°	Backrest height	480-550mm
Backrest width	455mm	Footrest-to-seat distance	390mm-470mm
Footrest clearance	155mm	Footrest length	240-370mm
Armrest-to-seat distance	220-850mm	Footrest-leg-angle	79°
Leg-to-seat-surface angle	270°	Armrest height	220-850
Armrest width	35mm	Armrest length	250
Armrest angle	3.55°	Distance between armrests	455
Hand rim diameter	525mm	Propelling wheel diameter	610mm
Castor wheel diameter	180mm	Total mass	17.3kg
Mass of heaviest part	14.3kg		
Static stability downhill	10.25°	Static stability uphill	10.35°
Static stability sideways	10.20°		
Parking brake			
Max slope uphill		7.0°	

Max slope downhill	7.10°

5. Indication for use

The K5 Wheelchair is to provide mobility to persons limited to a sitting position.

6. Comparison of technological characteristics with the predicate device

Device	Subject Device	Predicate Device	Results
510K Number	K260319	K232198	——
Manufacturer	Zhenjiang Assure Medical Equipment Co., Ltd.	Zhenjiang Assure Medical Equipment Co., Ltd.	——
Proprietary Name	Manual Wheelchair	Reclining wheelchair	——
Model	6 models	6 models	——
Classification	I	I	same
Indications for use	The K5 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, skirt guard	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull-to-Lock, Armrest, Backrest, Foot rest, skirt guard	Same
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)	1850mm(L)*1040mm(H) *16" 625mm(W) *18" 675mm(W) *20" 725mm(W)	1340 (L)* 1258 (H) *16" 625mm(W) *18" 675mm(W) *20" 725mm(W)	similar
Stowage length/width/height	1850*960*460mm(L*H*W)	1340 (L)* 1258 (H)*323mm(W)	similar
Weight(Total)	17.3kg	25.5kg	different*1
Weight Capacity	250LBS	350LBS	different*1
Seat Width	405mm	410-510mm	different*1
Seat height	520mm	525mm	different*1
Seat depth	400mm	460mm	different*1
Back type	Adjustable	Adjustable	same
Tires	Front: 178mm Rear:610mm	Front: 195mm Rear:613mm	different*1
Armrest	Detachable	Detachable	same
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	Foldable frame Push inward from left and right	Same

	sides to fold	sides to fold	
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 ISO16840-10	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	Comply with： ISO10993-1	same

Disscussion：

Different*1:	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, and so on. 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.

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 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices

ISO 7176-22:2014 Wheelchairs — Part 22: Set-up procedures

Biocompatibility

The biocompatibility of the subject device is based on the use of low-biocompatibility-risk materials and supporting information in accordance with Attachment G of FDA's 2023 Biocompatibility Guidance.

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 and effective as the legally marketed predicate device cleared under K232198.