August 6, 2026

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Fang (Fawn) Zhang
Director of Regulatory and Compliance
Yunyang Industrial Park Danyang City
#1 Baisheng Rd. Development Zone
Danyang Jiangsu, / 212300
China

Re: K261571
Trade/Device Name: Manual Wheelchair (H008, PCK7)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: May 11, 2026
Received: May 12, 2026

Dear Fang (Fawn) Zhang:

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,

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261571

Please provide the device trade name(s).

Manual Wheelchair (H008, PCK7)

Please provide your Indications for Use below.

The Manual Wheelchair is to provide mobility to people limited to sitting position.

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary - K261571

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Submitter's Name: Jiangsu Yuyue Medical Equipment & Supply Co., LTD.
Address: Yunyang Industrial Park Danyang City, Jiangsu 212300 China
Contact Person: Fang (Fawn) Zhang
Contact Title: JD. PharmD, RAC Director of Regulatory and Compliance
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Zip code: 212300
Telephone: (206) 639-1311

Date of Preparation: Jan.7th, 2025

2.0 Subject Device Information

Common Name: Manual Wheelchair
Proprietary Name: Manual Wheelchair
Model:H008, PCK7
Regulation Name: Wheelchair, Mechanical
Product Code: IOR
Regulation Number:890.3850
Regulation Class:1

3.0 Predicate Device Information

Manufacturer: Zhenjiang Assure Medical Equipment Co., Ltd.
Trade/Device: 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)
510(k) number: K232198

4.0 Indication for Use Statement

The Manual Wheelchair is to provide mobility to people limited to sitting position.

5.0 Subject Device Description

The subject device, mechanical wheelchair, is a manually operated device with wheels that is intended for medical purposes to provide mobility to people limited to

sitting position.
The 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 handgrips behind the seat for someone else to do the pushing.
The components include a frame, a backrest, a seat cushion, two handgrips, two removeable armrests, two armrest pads, two side panels, two rear wheels, two hand rims, two wheel locks, two front wheels with forks, and footrests with footplates.

The subject device has two models: Model H008 and Model PCK7

- H008: two 8 inch front wheels and two 24 inch rear wheels, a steel frame and a PVC upholstery that is flame resistant. Armrest is removeable. It has elevating legrest.
  Main materials: Steel (frame, armrest, wheel lock), PVC leather (armrest pad, backrest, seat cushion).
  Its maximum loading can not be over 150kgs (around 330lbs).
- PCK7: two 8 inch front wheels and two 24 inch rear wheels, a steel frame and a PVC upholstery that is flame resistant. Armrest is removeable. It has elevating legrest.
  Main materials: Steel (frame, armrest, wheel lock), PVC leather (armrest pad, backrest, seat cushion).
  Its maximum loading can not be over 225kgs(around 496lbs).

6.0 Technological Characteristic Comparison Table

Table 1 - General Comparison

Device	Subject Device	Predicate Device	Results
510(k) Number	K261571	K232198	--
Manufacturer	Jiangsu Yuyue Medical Equipment & Supply CO., LTD.	Zhenjiang Assure Medical Equipment Co., Ltd.	--
Proprietary Name	Manual wheelchair	Reclining wheelchair	Same
Model	H008, PCK7	YJ-011S 16”D, YJ-011S 16”DF, YJ-011S 18”D, YJ-011S 18”DF,YJ-011S 20”D, YJ-011S 20”DF	
Classification	I	I	Same
Indications for use	Manual Wheelchair is to provide mobility to people 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, X-Brace, Push-to-Lock, Armrest, Backrest, Footrest, skirt guard	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull-to-Lock, Armrest, Backrest, Foot rest, skirt guard	Similar
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) (mm)	H008: 1270×685×1280mm PCK7: 1320×770×1320mm (L*W*H)	1340 (L)* 1258 (H) *16" 625mm(W) *18" 675mm(W) *20" 725mm(W)	NOTE1
Stowage length/width/height (mm)	H008:1270×290×1280(L*W*H) PCK7:1320×400×1320(L*W*H)	1340 (L)* 1258 (H)*323(W)	NOTE2
Weight (Total)	H008:24kg PCK7:30kg	25.5kg	NOTE3
Weight Capacity	H008:150kg (around 330lbs) PCK7:225kg (around 496lbs)	350lbs	NOTE4
Seat Width	H008:500mm PCK7:610mm	410-510mm	NOTE5
Seat height	H008:500mm PCK7:480mm	525mm	NOTE6
Seat depth	H008:385mm PCK7:510mm	460mm	NOTE7
Back type	Adjustable	Adjustable	Same
Tires	Front: 193mm Rear:610mm	Front: 195mm Rear:613mm	NOTE8
Armrest	Removeable	fixed	NOTE9
Footrest	elevating legrest	Optional/ swing away Optional/ swing away	NOTE10
Rear Axle Position	Single	Single	Same
Frame Construction	Foldable frame Push inward from left and right	Foldable frame Push inward from left and	Same

	sides to fold	right 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 ISO7176-22 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： ISO10993-5 ISO10993-10 ISO10993-23	Comply with： ISO10993-5 ISO10993-10 ISO10993-23	Same

Summary of Substantial Equivalence Discussion:

NOTE1、2、3、5、6、7、8: Compared to the predicate device, the subject device has different value on the unfold size, stowage size, device weight, seat height, seat depth, and tire size. However, the subject devices have passed the ISO 7176-7-1998 and ISO 7176-5-2008, so the above different will not raise any new risk of safety or effectiveness.

NOTE 4: The Maximum loading is different with the predicate device. The subject manual wheelchair has already been tested for performance according to ISO 7176-1/-3/-8/-11/-13/-15 and complies with the standards. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

NOTE9: Compare the predicate device, the subject's armrest is Removeable. However, the subject device passed the test of ISO 7176-1/-8, so this difference will not raise any new risk of safety or effectiveness.

NOTE10: Compare the predicate device, the subject's foot rest is elevating legrest. However, the subject device passed the test of ISO 7176-1/-8, so this difference will not raise any new risk of safety or effectiveness.

Similar: Compare the predicate device, the subject's Wheel Lock is a push lock. However, the subject device passed the test of ISO 7176-3, so this difference will not raise any new risk of safety or effectiveness.

Despite of the above slight differences, the two devices all completed the

performance tests in accordance with ISO 7176 series standards. There are no safety and effectiveness aspects concerned.
In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The slight differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

7.0 Summary of Non-Clinical 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 subject 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 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 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 - Requirements and test method
ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures

Biocompatibility of User-contacting Parts

User-contacting material are carried out biocompatibility assessment in accordance with ISO 10993-1: 2018, including:
Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
Skin Sensitization per ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization.
Irritation per ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation.

8.0 Summary of Clinical Testing

No clinical study implemented for the wheelchair.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is as safe and effective as the legally marketed predicated device in K232198 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.