June 16, 2023

Ningbo Shenyu Medical Equipment Co., Ltd.
℅ Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K231110
Trade/Device Name: Manual Wheelchair (A006)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: March 13, 2023
Received: April 19, 2023

Dear Ms. 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,

Heather L. Dean -S

Heather Dean, Ph.D.
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Rehabilitation 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231110

Device Name
Manual Wheelchair (A006)

Indications for Use *(Describe)*
The A006 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

1. Submitter

K231110

Ningbo Shenyu Medical Equipment Co.,Ltd.
Address: No.1318 West of Tanjialing Road, Yuyao, Zhejiang, China
Contact Person: Ding Jianjun
Tel: +86- 574-62517777
Email: sales@shenyumedical.com

Submission Correspondent
Contact: Eva Li
Phone: + 86 (215) 881-7802
Email: eatereva@hotmail.com
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave, Shanghai, 200122 CHN

Prepared Date: May 10th,2023

2. Device

Name of Device: Manual Wheelchair
Common Name: Manual Wheelchair
Model(s): A006

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 subject device 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, leg rest strap, footrest, seat belt, brake

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:

Overall dimension	1000(L)*690(W)*875(H) mm		
Folded dimension	800(L)*325(W)*875(H) mm		
Seat width	425 mm	Seat plane angle	10.4 °
Seat depth	425 mm	Seat height from floor	445 mm
Backrest angle	21.1°	Backrest height	470 mm
Backrest width	430 mm	Footrest-to-seat distance	295 mm(min) 350 mm(max)
Footrest clearance	110 mm(min) 160 mm(max)	Footrest length	145 mm
Armrest-to-seat distance	260 mm	Footrest-leg-angle	98.0°(min) 100°(max)
Leg-to-seat-surface angle	109°	Front-armrest-to-backrest distance	260 mm
Front-armrest-to-backrest distance	430 mm	Armrest length	365 mm
Armrest width	55 mm	Armrest angle	4.3°
Distance between armrests	425 mm	Front location of armrest structure	440 mm
Hand rim diameter	Φ530 mm	Material	Aluminum
Horizontal location of axle	6 mm	Vertical displacement of wheel axle	73 mm
Weight of the device(net)	14.0 kg	Maximum weight bearing capacity of the device	100 kg
diameter of front wheels	Φ185 mm	diameter of rear wheels	Φ595 mm
Backpack carrier or permission	L：280 mm W：248 mm	Static stability sideways	15°

Static stability uphill	10°	Static stability downhill	10°
Minimum doorway entry depth		1250 mm	
Minimum turning radius		900 mm	
Minimum corridor width for side opening		1170 mm	
Parking brake			
Max slope uphill		12.9°	
Max slope downhill		10.6°	
Bake operating force		63.9 N	

5. Indication for use

The A006 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	K231110	——
Manufacturer	Ningbo Shenyu Medical Equipment Co., Ltd.	Ningbo Shenyu Medical Equipment Co., Ltd.	Same
Proprietary Name	Manual Wheelchair	Manual Wheelchair	Same
Model	A011	A006	——
Classification	I	I	Same
Indications for use	The A011 Manual wheelchair is to provide mobility to persons limited to a sitting position.	The A006 Manual Wheelchairs 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	1. Occupant-operated brake 2. Attendant-operated brake	Similar*2
Operation Environment	For indoor/outdoor us	For indoor/outdoor us	Same
Control Mode	Mechanical	Mechanical	Same
Size(unfold)	1100 (L)*660 (W) * 910 mm (H)	1000 (L)*690 (W)*875 (H) mm	Different*3
Stowage length/width/height	810 (L)*320 (W) * 930 mm (H)	800 (L)*325 (W)*875 (H) mm	Different*3
Weight(Total)	16 kg (35.2 lbs)	14 kg (30.9 lbs)	Different*3
Weight Capacity	136 kg(300 lbs)	100 kg(220 lbs)	Different*3
Seat Width	480 mm	425 mm	Different*3
Seat height	540 mm	425 mm	Different*3
Seat depth	420 mm	445 mm	Different*3
Back type	Fixed	Fixed	Same

Anti-tippers	Optional	Without Anti-tippers	Different*4
Tires	Front: 200 mm (8'') Rear: 610 mm (24'')	Front: 185 mm (7") Rear: 595 mm (23")	Different*3
Armrest	Flip back armrest	Fixed armrest	Different*5
Foot rest	Optional/swing away	Fixed/swing away	Different*5
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： ISO10993-1 ISO10993-5 ISO10993-10	Same

Disscussion：

Similar*1:	Compare the predicate device, the subject device adds two skirt guard which are 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 occupants clothes from getting caught in the wheels. This feature will not raise any new risk of safety or effectiveness.
Similar*2:	Compare the predicate device, the subject device adds attendant-operated brakes which the attendant can squeeze upwards the brake hand grip to brake the device. The subject device passed the test of <ISO 7176-3-2012 Part3: Determination of effectiveness of brakes>, so it will not raise any new risk of safety or effectiveness.
Different*3:	Compare the predicate device, the subject device has different values 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 difference will not raise any new risk of safety or effectiveness.
Different*4:	Compare the predicate device, the subject device does not equip Anti-tippers. However the subject device pass the test < ISO 7176-1-2014 Wheelchairs-Part1: Determination of static stability>, so this difference will not raise any new

	risk of safety or effectiveness.
Different*5:	Compare the predicate device, the subject's armrest is fixed, the foot rest is fixed as well. However, the subject device passed the test of <ISO 7176-8-2014 Wheelchairs- Part 8: Requirements and test methods for static, impact and fatigue strengths>, so this difference 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 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 Manual Wheelchair is as safe, as effective, as well as the legally marketed predicate device cleared under K201461.

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