July 21, 2022

Hebei Ruilangde Medical Equipment Technology Group Co., Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K220671
Trade/Device Name: Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: May 25, 2022
Received: May 25, 2022

Dear Ivy Wang:

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,

for Heather Dean, Ph.D
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)*
K220671

Device Name
Manual Wheelchair (Model: SYIV100-RLD-G01)

Indications for Use *(Describe)*
The Manual Wheelchair is intended for medical purposes 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.

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510(K) Summary

(As requirement by 21 CFR 807.92)

Date prepared: 21st, February, 2022

A. Applicant:

Name: Hebei Ruilangde Medical Equipment Technology Group Co., Ltd
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B. Device:

Trade Name: Manual Wheelchair (Model: SYIV100-RLD-G01)
Common Name: Manual Wheelchair
Model: SYIV100-RLD-G01

Regulatory Information
Classification Name: Wheelchair, Mechanical
Classification: Class I
Product code: IOR
Regulation Number: 21 CFR 890.3850
Review Panel: Physical Medicine

C. Predicate device:

K180852
Manual Wheelchair
JIANGYIN NEWRISE MEDICAL EQUIPMENT CO., LTD.

D. Device Description:

The Manual Wheelchair is a wheeled personal mobility device that incorporates a seat-support system for a person with a disability or a person without the full capacity to walk designed to be manually propelled by the user while seated in the device or by an attendant. The occupant moves the wheelchair by rotating two handrims protruding from rear wheels. An attendant moves the device by pushing or pulling handles on the device. The device can be folded for transport. The device can be operated indoor or outdoor on dry, smooth surfaces composed of concrete, blacktop or asphalt under normal driving conditions.

The subject manual wheelchair is a mechanical wheelchair with four wheels, including two front casters and two rear wheels, a frame made of carbon steel, a seat and a backrest made of oxford fabric, which is soft and water-resistant, two handles, armrests, handrims, foot pedals, legrest strap and seat belt. The subject manual wheelchair has a physical dimension of 1085mm × 700mm ×935mm (length × width × height). The device has a weight capacity of 100 kilograms, and its total mass is 17.3kg. The color is black.

Main Components and materials:

Main components	**Main materials**
Frame	Carbon steel
Back upholstery	Oxford fabric
Seat upholstery	Oxford fabric
Handle	PVC
Armrest	Polypropylene
Front casters	Polypropylene
Rear wheels	PU and aluminium alloy
Handrim	Polypropylene
Foot pedal	Polypropylene
Legrest strap	Leather
Seat belt	Nylon
Brake	PVC

The specification of the device is as below:

Main dimensions and structural parameters			
Overall dimension	1085mm × 700mm ×935mm (length × width × height)		
Folded dimension	900mm×300mm×750mm (length × width × height)		
Seat width	420mm	Horizontal angle of seat	14.4°
Seat depth	410mm	Backrest angle	22.3°

Seat height from floor	505mm	Angle of the legrest against the seat surface	108.5°
Distance between armrests	450mm	Distance from footrest to seat	425mm
Backrest height	405mm	Front position of armrest structure	370mm
Footrest height from floor	145mm	Diameter of armrest circle on rear wheels	525mm
Horizontal position of shaft	20mm		
Load capacity	100kg (220lb)		
Specification of front wheels	Φ195mm		
Specification of rear wheels	Φ598mm		
Main technical performance			
Static stability	longitudinal forward tilt ≥ 10°, longitudinal backward tilt ≥ 10°, flank tilt ≥ 15°		
Hill-holding performance	≥8°		
Sliding offset	≤350mm		
Minimum turning radius	≤850mm		
Minimum reversing width	≤1500mm		

E. Indications for Use:

The Manual Wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position.

F. Comparison of Technological Characteristics with the Predicate Device

Table 1 General Comparison of Proposed and Predicate Devices

Items	Proposed Device	Predicate Device	Result
510K #	K220671	K180852	-
Manufacturer	Hebei Ruilangde Medical Equipment Technology Group Co., Ltd	JIANGYIN NEWRISE MEDICAL EQUIPMENT CO., LTD.	-
Product Name	Manual Wheelchair	Manual Wheelchair	Same
Product Code	IOR	IOR	Same
Regulation Number	21 CFR 890.3850	21 CFR 890.3850	Same
Indications for use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same
Design Characteristic	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull-to-Lock, Armrest,	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull-to-Lock,	Same

	Backrest, Foot pedal	Armrest, Backrest, Footpad	
Operation Environment	For indoor/outdoor use	For indoor/outdoor use	Same

Table 2 Performance Comparison of Proposed and Predicate Devices

Items	Proposed Device	Predicate Device	Result
Overall Dimensions	Length: 1085mm Width: 700mm Height: 935mm	Length: 1030mm Width: 640 mm Height: 930 mm	Analysis
Rear Wheel	Size: 598 mm Tire Type: PU Solid Material Rim Diameter/Material: 525 mm/ Polypropylene	Size: 610mm Tire Type: PU Solid Material Rim Diameter/Material: 534 mm/ Steel Composite	Analysis
Wheel Lock	Pull-to-Lock	Pull-to-Lock	Same
Ground Clearance	150mm	150mm	Same
Min. Turning Diameter	1600mm	1700mm	Analysis
Armrest	Armrest material: Polypropylene Height-Adjustable: No	Arm pad: Padded Height-Adjustable: No	Analysis
Seat Dimensions	Depth: 410mm Height: 505mm Width: 420mm	Depth: 460 mm Height: 420 mm Width: 410 mm	Analysis
Casters	Size: 195 mm Tire Type: Polypropylene	Size: 200mm Tire Type: PVC Solid Material	Analysis
Weight of wheelchair	17.3kg	18kg	Analysis
Weight Capacity	100kg	100kg	Same
Folding mechanism	Push inward from left and right sides to fold	Push inward from left and right sides to fold	Same
Stowage length/width/height	900mm/300mm/750mm	Not Publicly Available	Analysis

Difference Analysis:

a. Overall dimensions and seat dimensions: the proposed device has minor difference with the predicate device, which will only affect the appearance of the device but not affect the safety and effectiveness of the subject manual wheelchair. The subject manual wheelchair has already been tested for performance according to ISO 7176-1/-3/-5/-7/-8/-11/-13/-15/-16/-22 and complies with the standards. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

b. Rear Wheel : the size, tire material and rim diameter of the proposed device are similar with the predicate device. The handrim material of the proposed device is different with the predicate device. The handrim of the proposed device has been tested for biocompatibility according to ISO 10993-5 and ISO 10993-10 and

complies with the requirements. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

c. Min. Turning Diameter, the proposed device has smaller min. turning diameter than predicate device, which meet the design specification and has better flexibility than predicate device. The subject manual wheelchair has already been tested for performance and complies with the standards. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

d. Armrest: the armrest of the proposed device is solid PP material while the armrest of the predicate device is padded. The PP material has been tested for biocompatibility according to ISO 10993-5 and ISO 10993-10 and it was proven to be safe. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

e. Casters: the proposed device has minor difference with the predicate device, which will only affect the appearance of the device but not affect the safety and effectiveness of the subject manual wheelchair. The material of casters is different with the predicate device. The PP material has been tested for biocompatibility according to ISO 10993-5 and ISO 10993-10 and it was proven to be safe. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

f. Weight of wheelchair, the proposed device has minor difference with predicate device, this different is caused by different framework design, but it could not affect the safety and effectiveness of proposed device. The subject manual wheelchair has already been tested for performance and complies with the standards. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

g. Although the stowage length, stowage width and stowage height of the predicate device are not available, the folding mechanism of the proposed device and the predicate device is same. In light of the slight difference of overall dimension between the proposed device and the predicate device, and the same folding way of the two devices, the difference of the stowage length/width/height between the devices can be considered as minor, which will not affect the safety and effectiveness of proposed device. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

Table 3 Safety Comparison of Proposed and Predicate Devices

Item	Proposed Device	Predicate Device	Result
Performance Test	Comply with ISO 7176-1/-3/-5/-7/-8/-11/-13/-15/-16/-22	Comply with ISO 7176-1/-3/-5/-7/-8/-11/-13/-15/-16/-22	Same
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Same
Label and labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same

G. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical Test

Non-clinical tests were conducted to verify that the proposed 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 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- 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 7176-16:2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices
- ISO 7176-22:2014 Wheelchairs — Part 22: Set-up procedures

Substantial Equivalence discussion:

The proposed device is substantially equivalent to the predicate device. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. 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, and performs as well as the legally marketed predicate device cleared under K180852.