March 1, 2019

Jiangyin Newrise Medical Equipment Co., Ltd
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401 Cn

Re: K180852
Trade/Device Name: Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: January 2, 2019
Received: January 7, 2019

Dear Ray 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180852

Device Name
Manual Wheelchiar

Indications for Use *(Describe)*
The device 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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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."

Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K180852

1. Date of Preparation

   02/27/2019

2. Sponsor

JIANGYIN NEWRISE MEDICAL EQUIPMENT CO., LTD.

No.97, WenXin Road, LinGang Street, JiangYin City, JiangSu Province,China 214400
Establishment Registration Number: Not yet registered or the Number
Contact Person: Huang Bing
Position: General Manager
Tel: +86-510-86092581
Fax: +86-510-89062698
Email: Top.Brian@inewrise.cn

3. Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, BeiJing, China 102401
Tel: +86-18910677558
Fax: +86-10-56335780
Email: ray.wang@believe-med.com

4. Identification of Proposed Device

Trade Name: Manual Wheelchair
Common Name: Mechanical Wheelchair
Model(s): XSG106A

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

Intended Use Statement:
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

5. Device Description

The proposed device, Manual Wheelchair model XSG106A, is traditional manually operated, user propelled, manual, mechanical wheelchairs. The device can be foldable easily for transport.

The main frame is made of magnesium alloy frame, the materials meet the standard of ASTM B107M-2012, and which has a seat base with four-wheeled with a back cover. Upon the outside of this framework, and to the rear, are assembled two axle plates, wheels are connected to the stainless steel axle receivers via stainless steel axles. On the front end of the frame are assembled two caster housings. Caster forks are mounted to these housings via steel axles. On the front end of the frame, upon the caster, two footplates are assembled for foot holding. Two armrests are mounted on the frame for user's arm holding. Two grips mounted on the top end of the frame with a brake, and another brake is designed under the seat base.

6. Identification of Predicate Device

Predicate #
510(k) Number: K163352
Product Name: Wheelchair
Manufacturer: Kunshan Hi-Fortune Health Products Co., Ltd.

7. Non-Clinical Test Conclusion

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 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 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 device.
ISO 7176-22:2014 Wheelchairs – Part 15: Set-Up Procedure
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.

8. Clinical Test Conclusion

No Clinical Test conducted.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Predicate Device (K163352)	Proposed Device	Remark
Product Code	IOR	IOR	SE
Regulation No.	21 CFR 890.3850	21 CFR 890.3850	SE
Class	1	1	SE
Intended 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.	SE
Design Characteristic	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull/Push-to-Lock, Armrest, Backrest, Footpad	Manual Operation, Four-Wheels, Foldable, Cross-Brace, Pull-to-Lock, Armrest, Backrest, Footpad	SE
Operation Environment	For Indoor/Outdoor use	For Indoor/Outdoor use	SE

Table 2 Performance Comparison

ITEM	Predicate Device (K163352)	Proposed Device	Remark
Overall Dimensions	Length: 1137 mm (44.8”) Width: 680 mm (26.8”) Height: 880 mm (34.6”)	Length: 1030 mm Width: 640 mm Height: 930 mm	Analysis
Rear Wheel	Size: 559 mm (22”) Tire Type: Rubber Rim Diameter/Material: 510.7 mm (20.1”)/Steel Composite	Size: 610 mm Tire Type: PU Solid Material Rim Diameter/Material: 534 mm/Steel Composite	Analysis
Wheel Lock	Pull-to-Lock, Push-to-Lock	Pull-to-Lock	SE
Ground Clearance	64 mm (2.5”)	150 mm	Analysis
Min. Turning Diameter	1915.2 mm (75.4”)	1700 mm	Analysis
Armrest	Arm pad: Paded Height-Adjustable: No	Arm pad: Padded Height-Adjustable: No	SE
Seat Dimensions	Depth: 420 mm (16.5”) Height: 470 mm (18.5”) Width: 410 mm (16.1”)	Depth: 460 mm Height: 420 mm Width: 410 mm	Analysis
Casters	Size: 152 mm (6”) Tire Type: PU	Size: 200 mm Tire Type: PVC Solid Material	Analysis
Weight of wheelchair	11.07kg	18kg	Analysis
Weight Capabity	100kg	100kg	SE

Difference Analysis:

a. Overall Dimensions, the proposed device has minor different overall dimensions with predicate device, this specification is only affects the appearance of the device, it could not affects the safety and effectiveness of proposed device. All performances of proposed device are meet the design

specification and been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

b. Rear Wheel, the proposed device has different rear wheel size and materials with predicate device, this specification is only affects the appearance of the device, it could not affects the safety and effectiveness of proposed device. All performances of proposed device are meet the design specification and been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

c. Ground Clearance, the proposed device has more ground clearance than predicate device, which is meet the design specification and has better trafficability characteristic than predicate device, and it also been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

d. Min. Turning Diameter, the proposed device has smaller min. turning diameter than predicate device, which is meet the design specification and has better flexibility than predicate device, and it also been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

e. Seat Dimensions, the proposed device has different seat dimensions with predicate device, this specification is only affects the appearance of the device, it could not affects the safety and effectiveness of proposed device. All performances of proposed device are meet the design specification and been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

f. Casters, the proposed device has different caster size and materials with predicate device, this specification is only affects the appearance of the device, it could not affects the safety and effectiveness of proposed device. All performances of proposed device are meet the design specification and been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

g. Weight of wheelchair, the proposed device has different weight of wheelchair with predicate device, this different is caused by different framework design, but it could not affects the safety and effectiveness of proposed device. All performances of proposed device are meet the design specification and been conducted into performance test, so the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

Table 3 Safety Comparison

ITEM	Predicate Device (K163352)	Proposed Device	Remark
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	SE
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

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.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.