Ot DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 28, 2017

Kunshan Hi-Fortune Health Products Co., Ltd.
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No.25 BanBiDian Rd.
LiYuan Town, TongZhou District, Beijing, 101121 CN

Re: K163352
Trade/Device Name: Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: June 22, 2017
Received: June 26, 2017

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S
2017.07.28 13:46:07 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163552

Device Name
Wheelchair

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.

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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."

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: K163352

1. Date of Preparation

   06/21/2017

2. Sponsor

Kunshan Hi-Fortune Health Products Co.,Ltd.

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Wheelchair
Common Name: Mechanical Wheelchair
Model(s): HM303

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, Wheelchair model HM303, 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, 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. A folden set is on the frame, under the grips, for folding backrest.

6. Identification of Predicate Device

Predicate #
510(k) Number: K153328
Product Name: SUNCO Mechanical Wheelchair
Manufacturer: Danyang Sunco Machinery 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:

Safety Testing
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 22 Set-up Procedures

Biocompatibility Performance
Cytotoxicity Test
Test Method: MTT Method, MEM with 10%FBS extract
Test Standard: ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
Test Result: Did not show potential toxicity

Skin Sensitization Test
Test Method: Guinea Pig Maximization Test, 0.9% Sodium Chloride Injection Extract & Sesame oil Extract
Test Standard: ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
Test Result: No significant evidence of causing skin sensitization.

Skin Irritation Test
Test Method: 0.9% Sodium Chloride Injection Extract & Sesame oil Extract

Test Standard: ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
Test Result: Negligible

8. Clinical Test Conclusion

No Clinical Test conducted.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate 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	Proposed Device	Predicate Device	Remark
Overall Dimensions	Length: 1137 mm (44.8”) Width: 680 mm (26.8”) Height: 880 mm (34.6”)	Length: 42” Width:25.2” Height:36”	Analysis
Rear Wheel	Size: 559 mm (22”) Tire Type: Rubber Rim Diameter/Material: 510.7 mm (20.1”)/Steel Composite	Size: 24” Tire Type: PU Solid Material Rim Diameter/Material: 21”/Steel Composite	Analysis
Wheel Lock	Pull-to-Lock, Push-to-Lock	Pull-to-Lock	SE
Ground Clearance	64 mm (2.5”)	2.3”	SE
Min. Turning Diameter	1915.2 mm (75.4”)	31”	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: 16” Height: 20” Width: 20”	Analysis
Casters	Size: 152 mm (6”) Tire Type: PU	Size: 7.9” Tire Type: PVC Solid Material	Analysis
Weight of wheelchair	11.07kg	38.6lb/17.5kg	Analysis
Weight Capabity	100kg	220lb/100kg	SE

Difference Analysis:

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.

Table 3Safety Comparison

ITEM	Proposed Device	Predicate Device	Remark
Performance Test	Comply with ISO 7176-1/-3/-5/-7/-8/-15/-16	Comply with ISO 7176-1/-3/-5/-7/-8/-15/-16	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

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.