September 22, 2021

Yongkang Dingchang Industry & Trade Co., LTD.
% Boyle Wang
Official correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 608, No. 738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K200423
Trade/Device Name: Electric Wheelchair (XW-LY001)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 11, 2021
Received: August 24, 2021

Dear Boyle 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,

Tushar Bansal -S

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

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)*
K200423

Device Name
Electric Wheelchair (XW-LY001)

Indications for Use *(Describe)*
The device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated 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

K200423

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

Name: YONGKANG DINGCHANG INDUSTRY & TRADE CO., LTD.
Address: NO.99, HUAXI ROAD, XICHENG STREET, YONGKANG CITY, ZHEJIANG PROVINCE, 321300 CHINA
Tel: 86- 13429055889
Fax: 86- 579-87321558
Contact: Tony Chen
Date of Preparation: Sep.21.2021

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Electric Wheelchair
Common name: Powered wheelchair
Classification name: Wheelchair, Powered
Model(s): XW-LY001

3.0 Classification

Production code: ITI
Regulation number: 21 CFR 890.3860
Classification: Class II
Panel: Physical Medicine

4.0 Predicate Device Information

Manufacturer: Nanjing Jin Bai He Medical Apparatus Co., Ltd.
Device: Powered Wheelchair DYW30A(D09)

510(k) number: K170787

5.0 Indication for Use Statement

The device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.

6.0 Device Description

The Model XW-LY001 Electric wheelchair is powered by Li-ion battery, driven by DC motor. Users control direction and adjust speed by controller.
It is suitable to be used in low speed, good road condition and small slope.
The electric wheelchair consists of two foldable armrests, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, a Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.
The subject device has 8 inch front wheel and 12.5 inch rear wheel.
The motor of electric wheelchair is DC24V 200W; the battery is 25.2V 10.4Ah Li-ion battery; the charger is DC 24V, 2A.
Max. loading can not be over than 125Kgs, and its maximum speed is 6km/h.
The braking time is about 2-3s,and the braking distance is ≤1.5m

7.0 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 7176-2:2017 Wheelchairs - Part 2:Determination of dynamic stability of electrically powered wheelchairs.
ISO 7176-3:2012 Wheelchairs – Part 3: Determination of effectiveness of brakes.
ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range.
ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space.
ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs.
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 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs.
ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of

electrically powered wheelchairs.
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 7176-14:2008 Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods;
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 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22:2014 Wheelchairs - Part 22 Set-up Procedures
ISO 7176-25:2013 First edition 2013-07-15Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

Biocompatibility of patient-contacting parts

Statement for Biocompatibility Certification

The Joystick knob, Joystick Gaiter, Enclosure Moulding(s), and Keypad of the Electric Wheelchair, XW-LY001 in its final finished form are identical to the Joystick knob, Joystick Gaiter, Enclosure Moulding(s), and Keypad of the Y207 Electric Wheelchair (JIANGSU INTCO MEDICAL PRODUCTS CO., LTD., K202482, clearance date 03/18/2021) in formulation, processing, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The patient-contacting materials of Electric Wheelchair, XW-LY001 have the same nature of tissue contact and contact duration as the Y207 Electric Wheelchair.

Other patient-contacting material are carried out biocompatibility assessment in accordance with IS0 10993-1: 2018, including :
Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
Irritation and Skin Sensitization per ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

8.0 Clinical Test Conclusion

Clinical testing was not required for this submission.

9.0 Comparison to Predicate Device and Conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the model XW-LY001 Electric Wheelchair is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Table1- General Device Characteristics Comparison Table

Characteristic	Subject Device	Predicate Device	Justification for Substantial Equivalence
Proprietary name,	Electric Wheelchair	Powered Wheelchair	--
Manufacturer	YONGKANG DINGCHANG INDUSTRY & TRADE CO., LTD.	Nanjing Jin Bai He Medical Apparatus Co., Ltd.	
Model(s)	XW-LY001	DYW30A(D09)	--
510(k) number	K200423	K170787	--
Frame Material	Aluminium alloy	Aluminium alloy	Same
Frame Design/Style	Foldable/ The device consists of a foldable and non-rigid type of power wheelchair base with rear drive and 2 casters in the front and two anti-tippers in the rear.	Foldable/ The device consists of a foldable and non-rigid type of power wheelchair base with rear drive and 2 casters in the front and two anti-tippers in the rear.	Similar
Folding Mechanism	A foldable seat frames (The backrest could be folded to seat)	A foldable seat frames (The backrest could be folded to seat)	Same
Product Structure	Consists of two foldable armrests, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, a Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.	Consists of two foldable armrests, a seat belt, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, two Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller	The subject device has no seat belt. Related precautions and warnings for use the device and the information of operating surface and max. slope have clearly defined in the user manual.
Overall Dimensions			

Length	37.4”	37.4”	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Width	25.6”	22.6”	
Height	38.4”	36.2”	
Seat Dimensions			
Width	18.5”	Not publicly available	/
Depth	16.9”	Not publicly available	/
Height	19.3”	Not publicly available	/
Folded Dimensions			
Length	30.5”	Not publicly available	/
Width	25.6”	Not publicly available	/
Height	13.8”	Not publicly available	/
Wheelchair Weight			
With batteries	27.8kg /61 lbs	51.8” lbs. / 23.5 kg	The difference will not raise any new safety and effectiveness concerns
Without batteries	25.8kg /55.6 lbs	Not publicly available	/
Controller	PG DRIVES TECHNOLOGY LTD., newVSi	Changzhou Billon Electronic Appliance Co., Ltd., WS-1	Although different controller is used, both the control system, including the joystick controller, the electromagnetic brakes and the user interface are similar. The joystick controls the directions and speed of movement, and when the joystick is released, the powered wheelchair will slow down to stop and the brakes will automatically re-engage. The controller also provides the battery status displaying and abnormal condition displaying. Both of the control systems are evaluated according to

			standard ISO 7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Drive Style (e.g., rear, mid, front)	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Motor Type	Brushed DC motor	Brushless DC motor	The minor differences will not impact the safety and effectiveness of the substantial equivalence.
Motor Output	DC 24V x 200W*2 pcs	24 VDC *250W *2 pcs	
Batteries	Kunshan Hi-Fortune Health Products Co.,Ltd	Jiangsu Feng Chi Green Power Supply Co., Ltd.	
Quantity	1pcs	2 pcs	
Type	FH2410	ITP2406	
Chemistry	Lithium-ion	Lithium-ion	
Range per Charge	15.5 miles (25km)	11.2 miles (18 km)	There is a larger cruising range for the subject device.
Charger Type (On-board/Off-board/ Carry-on)	Off-board	Off-board	Same
Input/Output Power	DC 25.2 V, 10.4 Ah	24 VDC, 6 Ah	The minor differences will not impact the safety and effectiveness of the substantial equivalence.
Brake	Smart Electromagnetic brake	Smart Electromagnetic brake	Same
Minimum braking distance and time	≤1.5 m,0.8s	1m	Our minimum braking distance is a little bigger thanthe predicate device. There is no new safety and effectiveness concerns raised due to the difference
Max speed			
Forward	3.75 mph (6 km/h)	3.75 mph (6 km/h)	Same
Reverse	1.79 mph(2.88 km/h)	1.86 mph (3.0 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness.
Rear Wheels Size	12.5” x 2.25”(320 x 57 mm)	12.5” x 2.25”(320 x 57 mm)	Same

Quantity	2	2	Same
Tire Pressure (if pneumatic)	2kgf/m²	PU solid tire	/
Castors Size	8”x1.97”(200 x 50mm)	7”x1.77” (180 x 45 mm)	Larger sizes of front wheels bring steadier pivoting function than predicate device.
Quantity	2	2	Same
Tire Pressure (if pneumatic)	PU solid tire	PU solid tire	Same
Anti-tip Wheels	2”x0.4”(48 x10mm)	Not publicly available	/
Removable (Yes/No)	No	No	Same
Maximum Occupant Mass	125kg/ 276 lbs.	120kg/ 264 lbs.	Large loading weight means more convenient for the User.
Curb Climbing ability	1.97 ”(50mm)	1.36” (34.5 mm)	The larger height in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Ground clearance	25mm	Not publicly available	/
Minimum Turning Radius	≤42.2”(≤1.2m)	32.8” (833 mm)	The difference in the turning radius will bring more convenience when it turns. The difference will not raise any new safety and effectiveness concerns.
Maximum Incline	10 degrees	8 degrees	Larger safe operational incline of subject bring more convenient for the use environment
Footplates	Plastic	Not publicly available	/
Back Upholstery	Oxford cloth	PVC Vinyl	Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concerns due to the difference.
Armrest Type	Unadjustable	Not publicly available	/
Operating surface & environment	Indoor	Indoor	Same
Additional Accessory	Electronic items: 1 year	Not publicly available	/

Warranty	Frame: 5 years		

Summary of substantial equivalence discussion:

The XW-LY001 Electric wheelchair complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2001, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 7176-16:2012, ISO 7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013,IEC 62133:2012, ISO 10993-1:2018, ISO10993-5:2009, ISO 10993-10:2010. The intended uses for both devices are the same. Mainframes of two devices are folded by way of front and rear close, and frame materials all meet the Tensile Strength, Yield Load, and Elongation tests. The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14:2008. Software validation is carried out on both control systems. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3:2012. Maximum obstacle climbing and Maximum safe operational incline are slightly different while such differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns as well as both meet the requirements of the ISO 7176-2:2001, ISO 7176-10:2008. The biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2010. The flame retardant test of the seat cushion/back cushion and armrest of both subject device and predicate device is carried out according to the ISO 7176-16 test. Therefore, both devices are assured to be under the same safety level. 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 differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

10.0 Conclusion

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