January 10, 2022

Zhejiang Qianxi Vehicle Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K212854
Trade/Device Name: Powered Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 8, 2021
Received: October 13, 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,

for Heather Dean, PhD
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)*
K212854

Device Name

Powered Wheelchair (Model:XFGW30-107, XFGW25-203)

Indications for Use *(Describe)*
The XFGW30-107 and XFGW25-203 Powered Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. This product is suitable for disabled people with mobility difficulties and elderly people.

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

K212854

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

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Date of Preparation: Dec.20,2021

Designated Submission Correspondent

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2.0 Device information

Trade name: Powered Wheelchair
Common name: Powered Wheelchair
Classification name: Powered Wheelchair
Model(s): XFGW30-107,XFGW25-203

3.0 Classification

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

4.0 Predicate device information

Manufacturer: JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
Trade/Device: Y207 Electric Wheelchair
510(k) number: K202482

5.0 Indication for Use Statement

The XFGW30-107 and XFGW25-203 Powered Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. This product is suitable for disabled people with mobility difficulties and elderly people.

6.0 Device description

The subject device, Powered Wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick and adjusting speed.
The Powered Wheelchairs consist of two foldable armrests, a backrest, a seat cushion, a safety belt, 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 XFGW30-107 and XFGW25-203 Powered Wheelchair is intended to provide mobility to a disabled or elderly person limited to a seated position.

Folding design: This foldable electric wheelchair has main frame, rear frame, backrest frame, seat frame, front wheel frame and battery frame. Release the locking device of the backrest frame and the rear frame, push the backrest frame downward, drive the seat frame to rotate toward the backrest frame with the rotating mechanism, the two armrest frames rotate towards the direction of the seat frame. At the same time two front wheel frames move to the direction of the seat frame. When the back cushion is in contact with the seat cushion, the folding is completed.

Joystick: This controls the speed and direction of the wheelchairs. Push the joystick in the direction you wish to go. The further you push it, the faster the speed. Releasing the joystick stops the wheelchair and automatically applies the brakes.

Controller: The controller includes a power switch, speed adjustment/driving module Indicator, speed/driving module decreasing button, speed/driving module increasing button, a horn button and a direction joystick. The operation interface controller receives the operation signal and transmits it to the main board of the controller body, and sends a control signal to the electric wheelchair to adjust and operate the electric wheelchair.

Wheel and frame connection method: First, the left and right frames are connected to the motor respectively, and then the motor shaft is connected to the wheel. The motor rotates to drive the wheels to rotate to drive the wheelchair.

Frame design: 1. The frame of this product is aluminum tube. 2. The operation mode of the folding mechanism is to remove the locking device by someone else and

manually push the backrest frame to complete the folding operation under non-riding state.

The Powered Wheelchair has 8 inch front wheel and 12.5 inch rear tire.
The motor of electric wheelchair is DC24V 180W; the battery is 24V 12AH, Li-ion battery; the charger is 24V/4A.
Max. loading can not be over than 100Kgs.
Max. distance of travel on the fully charged battery is 22km and Max. speed forward is 6km/h.
The braking time is about 2s, and the braking distance is ≤1.5m.

The subject device that can be used on both indoor and outdoor surfaces (i.e., concrete, asphalt, indoor flooring such as carpet, gravel, grass, and bark/woodchips).

The following surfaces are recommended NOT to operate on:
- Wet or icy surface
- Road maintenance hole metal cover
- Do not use on stairs
- Do not use escalators. Use the elevator.
- Too steep incline over 12 degrees.
- Obstacle climbing ability: 1.57”(40mm)

7.0 Summary of Non-Clinical Testing

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 overall 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 devices
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
IEC 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 62133-2:2017 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 Part 2: Lithium systems
EN 12184 :2014 Electrically powered wheelchairs, scooters and their chargers- Requirements and test methods

Biocompatibility of patient-contacting parts

Patient-contacting material are carried out biocompatibility assessment in accordance with lSO 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 Summary of Clinical Testing

No clinical study implemented for the electric wheelchair.

9.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Proposed device		Predicate device	Remark
Product Code	ITI		ITI	Same
Regulation No.	21 CFR 890.3860		21 CFR 890.3860	Same
Class	II		II	Same
Product name	Powered Wheelchair		Y207 Electric Wheelchair	-
510(k) No.	K212854		K202482	-
Models	XFGW30-107	XFGW25-203	Y207	-
Intended Use	The XFGW30-107 and XFGW25-203 Powered Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. This product is suitable for disabled people with mobility difficulties and elderly people.		The Y207 Electric Wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. This product is suitable for disabled people with mobility difficulties and elderly people.	Same
Use environment	Indoor and outdoor use		Indoor and outdoor use	Same
Patient Population	This product is suitable for disabled people with mobility difficulties and elderly people.		This product is suitable for disabled people with mobility difficulties and elderly people.	Same
Product structure	Consist of two foldable armrests, a backrest, a seat cushion, a safety belt, 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 device consists of two parts: the electrical part and the wheelchair main body. The electrical part includes motor, battery box, controller and charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, seat and back upholstery.	Similar
Driving system	Direct drive on the rear wheels		Direct drive on the rear wheels	Same
Number of wheels	4		4	Same
Main frame material	Aluminium alloy		Aluminium alloy	Same
Motor	Brushless motor, DC24V* 180W*2pcs		Brushless motor, 24 VDC *200W * 2 pcs	Minor differences in the dimensions will not impact the safety and effectiveness of the
Battery	DC 24V 12Ah Lithium-ion, 2 pcs		Lithium-ion 20 Ah x 24 VDC	
Battery charger	Off-board charger		Off-board charger	

	Input: 100-240 VAC Output: DC 24V, 4A (3A)	Input: 100-240 VAC Output: DC 24V, 6 Amp	substantial equivalence.

Table2 Performance Comparison

Item	Proposed Device		Predicate Device	Remark
	XFGW30-107	XFGW25-203		
Dimensions (mm)	1100 x 630 x 960		1110 x 700 x 980	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Folded dimensions (mm)	750x630x375		810 x 700 x 400	Minor differences in the folded dimensions will not impact the safety and effectiveness of the substantial equivalence.
Weight, w/ Battery	71.65 lbs. /32.5kg		Not publicly available	The difference will not raise any new safety and effectiveness concerns.
Frame design	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 two parts: the electrical part and the wheelchair main body. The electrical part includes motor, battery box, controller and charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, seat and back upholstery.	Same
Folding mechanism	A foldable seat frames (The backrest could be folded to seat)		Not publicly available	The folding mechanism of the predicate device is not publicly available. No impact on safety and effectiveness.
Front wheel(inch)	8 (PU solid tire)		8 (PU solid tire)	Same
Rear tire (inch)	12.5 (Pneumatic tire)		10 (PU solid tire)	Larger sizes of front wheels bring steadier pivoting function than predicate device.
Cruising Range(km)	22		20	There is a larger cruising range for the subject device.

Obstacle climbing(mm)	40	50	The smaller height in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Static stability forward	30°	Not publicly available	Both of the devices are evaluated according to standard ISO 7176-1:2014, so the different static stability will not impact the safety and effectiveness
Static stability rearward	17°		
Static stability sideways	14°		
Max. loading (kg)	220lbs(100kg)	275lbs (125kg)	Less loading weight means more convenient for the transportation
Maximum safe operational incline	12 degrees	8 degrees	Larger safe operational incline of subject bring more convenient for the use environment
Min. Turning radium	1200mm	950mm	The difference in the turning radius will bring more convenience when it turns. The difference will not raise any new safety and effectiveness concerns.
Minimum braking distance	1.5m	1.5m	Same
Max Speed Forwards	1.7m/s (6 km/h)	1.5m/s (5.4 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Max. Speed Backward	0.7m/s (2.52 km/h)	0.8m/s (2.88 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Controller	Shanghai Micon Mechanical & Electrical Co., Ltd. M7084	PG Drives Technology Ltd., newVSI	Different 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.
Speed control method	Joystick control method	Joystick control method	Same

Table3 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Materials contacting user	Armrest: PU; Backrest/Seat: sandwich mesh fabric (polyester) M7084 controller: Controller Buttons/ joystick: Silicone rubber	Armrest: PU; Backrest/seat: sandwich mesh fabric (polyester) newVSi electric wheelchair controller: Joystick knob: Santoprene 101-80; Joystick Gaiter: Silicone 3032 (50%) & 5031 (50%) Enclosure Moulding(s): ABS/PC Wonderloy PC-540 Keypad: Silicone keypad coatings TC-2407 & CH-6330	Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concerns due to the difference.
Biocompatibility of materials contacting user	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Same

Summary of substantial equivalence discussion:

The Powered Wheelchair model XFGW30-107 and XFGW25-203 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, IEC 60601-1-2: 2014, IEC 62133-2:2017, 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 in K202482 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.