



June 9, 2022

Kunshan Hi-Fortune Health Products Co., Ltd.  
% Boyle Wang  
Shanghai Truthful Information Technology Co., Ltd.  
RM.1801, No.161, East Lujiazui Rd., Pudong  
Shanghai, Shanghai 200120  
China

Re: K212503

Trade/Device Name: Electrically Powered Wheelchair (Model: HP458E)  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered Wheelchair  
Regulatory Class: Class II  
Product Code: ITI

Dear Boyle Wang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 18, 2022. Specifically, FDA is updating this SE Letter to update the contact name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Heather Dean, OHT5: Office of Neurological and Physical Medicine Devices, 240-402-9874, [Heather.Dean@fda.hhs.gov](mailto:Heather.Dean@fda.hhs.gov).

Sincerely,

**Heather L. Dean -S**

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



January 18, 2022

Zhejiang Qianxi Vehicle Co., Ltd.  
% Boyle Wang  
Shanghai Truthful Information Technology Co., Ltd.  
RM.1801, No.161, East Lujiazui Rd., Pudong  
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Regulatory Class: Class II  
Product Code: ITI  
Dated: October 14, 2021  
Received: October 20, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Heather L. Dean -S**

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Assistant Director, Acute Injury Devices Team  
DHT5B: Division of Neuromodulation  
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## Indications for Use

510(k) Number (if known)  
K212503

Device Name  
Electrically Powered Wheelchair (Model: HP458E)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## **510(k) Summary**

### **(K212503)**

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: Kunshan Hi-Fortune Health Products Co.,Ltd.  
Address: No. 625,Juxiang Road,Zhangpu Town,Kunshan City,Jiangsu Province,China  
Tel: 86-512-55195100  
Contact: Mr.Jianjiang Fan  
Date of Preparation: Dec.20,2021

#### **Designated Submission Correspondent**

Mr. Boyle Wang  
Shanghai Truthful Information Technology Co., Ltd.  
Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China  
Tel: +86-21-50313932  
Email: Info@truthful.com.cn

#### **2.0 Device information**

Trade name: Electrically Powered Wheelchair  
Common name: Powered Wheelchair  
Classification name: Powered Wheelchair  
Model(s): HP458E

#### **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 proposed device, Electrically Powered Wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick and adjusting speed.

The Electrically Powered 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 electric wheelchair is intended to provide mobility to a person with a disability or an older adult limited to a sitting 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 wheelchair. 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, a speed adjustment 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 tube of this product is mostly 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 subject device has 6 inch front wheel and 10 inch rear tire.

The motor of electric wheelchair is DC24V 120W; the battery is 25.2V 10.4AH, Li-ion battery; the charger is 24V/2A.

Max. loading can not be over than 120Kgs.

The following surfaces are recommended NOT to operate on:

- Sand surface
- 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 6 degrees.  
Obstacle climbing ability: 1.97"  
Do not use outdoors

## **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 7176-13 : 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  
ISO 7176-25:2013 Wheelchairs - 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 VR2 Controller/Joystick of the Electrically Powered Wheelchair, model HP458E, are identical to the VR2 Controller/Joystick of the KARMA Power Wheelchair, model KP-10.3S, manufactured by KARMA Medical Products Co., Ltd., under K202506, cleared on January 16, 2021 in formulation, processing, sterilization, and geometry, and no other chemicals have been added.

The VR2 Controller/Joystick of the HP458E Electrically Powered Wheelchair has the same nature of tissue contact and contact duration (Surface device category, intact skin contact, less than 24-hour duration) as Karma Powered Wheelchair, KP-10.3S.

Other patient-contacting material are carried out biocompatibility assessment in accordance with ISO 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	Electrically Powered Wheelchair	Powered Wheelchair DYW30A(D09)	-
510(k) No.	K212503	K170787	-
Models	HP458E	DYW30A(D09)	-
Intended Use/ Indications for use	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.	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.	Same
Use environment	Indoor use	Indoor use	Same
Patient Population	The electric wheelchair is intended to provide mobility to a person with a disability or an older adult limited to a sitting position	The electric wheelchair is intended to provide mobility to a person with a disability or an older adult limited to a sitting position	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.	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.	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	DC24V* 120W*2pcs	24 VDC *250W * 2 pcs	Minor differences in the dimensions will not impact the safety and
Battery	DC 25.2V 10.4Ah Lithium-ion, 2 pcs	Lithium-ion, ITP2406 6 Ah x 24 VDC x 2 pcs	

			effectiveness of the substantial equivalence.
Battery charger	High Power Technology Inc. HP0060W(L2) Input: 100-240 VAC Output: DC 24V, 2 Amp	High Power Technology Inc. HP0060W(L2) Input: 100-240 VAC Output: DC 24V, 2 Amp	Same

**Table2 Performance Comparison**

Item	Proposed Device	Predicate Device	Remark
Dimensions	39.0"x24.4"x34.6"	37.4" x 22.6" x 36.2"	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Folded Dimensions	28.3"x13.4"x28.0"	Not publicly available	The folded dimensions are not publicly available, but no impact on safety and effectiveness.
Weight, w/ Battery	41.9 lbs. /19.0kg	51.8" lbs. / 23.5 kg	Less weight will lead to more convenience when transported and there is more cruising range than predicate device.
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 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.	Same
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
Front wheel(inch)	6 (PU solid tire)	7 (PU solid tire)	Smaller sizes of front wheels, The difference will not raise any new safety and effectiveness concerns.
Rear tire (inch)	10 (PU solid tire)	12.5 (PU solid tire)	Smaller sizes of rear wheels, The difference will not raise any new safety and effectiveness concerns.
Cruising	15	18	There is a smaller cruising

Range(km)			range for the subject device.
Obstacle climbing(mm)	50	34.5	The larger height in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Max. Speed (km/h)	6	6	Same
Static stability forward	16.5°	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	16.5°		
Static stability sideways	17°		
Max. loading (kg)	264lbs (120kg)	264lbs (120kg)	Same
Maximum safe operational incline	6 degrees	8 degrees	Small safe operational incline of subject device.
Min. Turning radius	1000mm	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 obstacle climbing	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.
Minimum braking distance	1m	1m	Same
Max Speed Forwards	3.75 mph (6 km/h)	3.75 mph (6 km/h)	Same
Max. Speed Backward	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
Controller	PG Drives Technology Ltd., VR2	Changzhou Billon Electronic Appliance Co.,Ltd., WS-1	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
Main materials	Frame: Aluminium alloy; Wheel, Armrest: PU; Backrest/ Cushion/Seat: Terylene	Frame: Aluminium alloy; Wheel, Armrest: PU; Backrest: PVC Vinyl	Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concerns due to the difference.
Materials contacting user	Armrest: PU; Backrest/Cushion/Seat:Terylene VR2 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	Armrest: PU; Seat: PVC Vinyl Backrest: PVC Vinyl Safety belt: PVC Vinyl Joystick: PVC Vinyl	
Biocompatibility of materials contacting	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009),	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009),	Same

user	Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same
Level of Concern of the Software	Moderate	Moderate	Same

**Summary of substantial equivalence discussion:**

The Electrically Powered Wheelchair model HP458E 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 62133:2012, 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 in K170787 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.