September 28, 2021

Kunshan Hi-Fortune Health Products Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
Rm. 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K201855
Trade/Device Name: Electrically Powered Wheelchair - Model HP358E
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 17, 2021
Received: September 7, 2021

Dear Mr. 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, PhD
Assistant Director, Acute Injury Device 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)*
K201855

Device Name
Electrically powered wheelchair - Model HP358E

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

(K201855)

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.
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Date of Preparation: Sep.23,2021

Designated Submission Correspondent

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2.0 Device Information

Trade name: Electrically Powered Wheelchair - Model HP358E
Common name: Powered wheelchair
Classification name: Wheelchair, Powered
Model(s): HP358E

3.0 Classification

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

4.0 Predicate Device &Reference Device Information

Predicate Device:
Manufacturer: Nanjing Jin Bai He Medical Apparatus Co., Ltd.

Device: Powered Wheelchair, DYW30A(D09)
510(k) number: K170787

Reference Device: K070501, Ruike 3421 powered wheelchair, Shanghai Ruike Sports Goods Co , Ltd.(Reference for biocompatibility of controller / joystick)

5.0 Device Description

The Electrically Powered Wheelchair - Model HP358E is powered by Li-ion battery, driven by DC motor. Users control direction and adjust speed by controller.
The main frame of the wheelchair is made of aluminum alloy which is complied with the standard of ASTM B221, and there is a seat base with four-wheeled and two with a back cover on the frame. 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. There are two rear caster wheels in back and anti-tip wheels in front to prevent the power chair from tipping. On the front end of the frame, upon the caster, a foot platform is assembled for foot holding.Two non-adjustable 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. The backrest can be adjusted by squeezing yellow catches on the back together. A storage compartment located between the seat and foot platform. The joystick can be mounted on the left or right side using the quick release mechanism.

The subject device has two 2 inch Anti-tippers, two 8 inch front wheels and two12 inch rear wheels.
The motor is DC24V 250W; the battery is 25.2 V 10.4Ah Li-ion battery; the charger is DC 24V, 2A.
Max. loading can not be over than 125Kg, the maximum distance of travel on the fully charged battery is 10km and its maximum speed is 6km/h.
The braking time is about 2~3s, and the braking distance is ≤1.0m

Due to the device design of the body structure the following conditions are recommended NOT to operate in:
- The wheelchair is not intended for use on roads, streets, or highways.
- Do not use on an escalator
- Do not use while lifting weights.
- This device is not safe for use with or around a MRI machine. Do not use in the vicinity of a MRI machine
- Never use the device to negotiate steps or escalators.
- Turning Diameter :1460mm
- Ground Clearance :13mm
- Maximum safe operational incline:10°

6.0 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.

7.0 Non-Clinical Test Summary

Non-Clinical Performance Testing:

The following non-clinical data were provided in support of the substantial equivalence determination:
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
EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods.

IEC 60601-1: 2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
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 materials of the Joystick knob,Joystick Gaiter, Enclosure Mouldings and Keypad of M7084 controller&Joystick of the Electrically Powered Wheelchair, model HP358E, manufactured by Kunshan Hi-Fortune Health Products Co.,Ltd, are identical to the materials of M7084 controller&Joystick of Ruike 3421 powered wheelchair, Shanghai Ruike Sports Goods Co., Ltd., K070501, clearance date February 12, 2007, in formulation, processing, and geometry, and no other chemicals have been added.
The patient-contacting materials of the M7084 controller&Joystick of the Electrically Powered Wheelchair, HP358E, has the same nature of tissue contact and contact duration (e.g., surface device category, intact skin contact, less than 24-hour duration) as the Ruike 3421 powered 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.

Software Information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

8.0 Clinical Test Conclusion

Clinical testing was not required for this submission.

9.0 Comparison to Predicate Device

The technological characteristics, features, specifications, materials, mode of

operation, and intended use of the Electrically Powered Wheelchair - Model HP358E 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

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 - Model HP358E	Powered Wheelchair DYW30A(D09)	-
510(k) No.	K201855	K170787	-
Models	HP358E	DYW30A(D09)	-
Intended 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	Aluminium alloy	Aluminium alloy	Same

material			
Motor	Brushless DC motor 250W x 24 VDC x 2 pcs	24 VDC *250W * 2 pcs	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Battery	Lithium-ion, FH2410 10.4Ah x25.2VDCx1 pc	Lithium-ion, ITP2406 6 Ah x 24 VDC x 2 pcs	
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	

Table2 Performance Comparison

Item	Proposed Device	Predicate Device	Remark
Dimensions	960mm*635mm*880mm (37.8”x25.0”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.
Weight, w/ Battery	59.15lbs/27.2kg	51.8” lbs. / 23.5 kg	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 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)	8 (PU solid tire)	7 (PU solid tire)	Larger sizes of front wheels bring steadier pivoting function than predicate device.
Rear tire (inch)	12 (Pneumatic tire)	12.5 (PU solid tire)	Smaller sizes of rear wheels, The difference will not raise any new safety and effectiveness concerns.
Cruising	10	18	There is a shorter cruising

Range(km)			range for the subject device.
Obstacle climbing(mm)	2.36”(60mm)	1.36” (34.5 mm)	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	22.4°	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	18.2°		
Static stability sideways	23°		
Max. loading (kg)	275lbs(125kg)	264lbs (120kg)	Larger loading weight means more convenient for the user
Maximum safe operational incline	10 degrees	8 degrees	Larger safe operational incline of subject bring more convenient for the use environment
Min. Turning radium	57.5”(1460mm)	32.5” (833 mm)	The subject turning radius is larger and may limit where the device can be used. The difference will not raise any new safety and effectiveness concerns.
Maximum obstacle climbing	2.36”(60mm)	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	1.80 mph (2.9 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	Shanghai Micon Mechanical&Electrical	Changzhou Billon	Different

	Co.,Ltd., M7084.	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.
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: Leather; Backrest: 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: Terylene Seat: Terylene Joystick: ABS	Armrest: PU; Seat: PVC Vinyl Backrest: PVC Vinyl Safety belt: PVC Vinyl Joystick: PVC Vinyl	
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
Label and	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

Labeling	Requirements	Requirements	
Level of Concern of the Software	Moderate	Moderate	Same

Summary of substantial equivalence discussion:

The Electrically Powered Wheelchair model HP358E 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 and raises no new questions of safety or effectiveness. The subject device Electrically Powered Wheelchair - Model HP358E is substantially equivalent to the predicate device in K170787.