October 17, 2024

Kunshan Hi-Fortune Health Products Co., Ltd
% Ariel Xiang
Consultant
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
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China

Re: K241337
Trade/Device Name: Electrically powered wheelchair (HP202)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: September 16, 2024
Received: September 16, 2024

Dear Ariel Xiang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Devices Team
DHT5B: Division of Neuromodulation and Rehabilitation 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241337

Device Name

Electrically powered wheelchair

Indications for Use *(Describe)*

It 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.

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
K241337

Document Prepared Date: 2024/5/11

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B. Device:

Trade Name: Electrically powered wheelchair

Common Name: Powered wheelchair

Models: HP202

Regulatory Information

Classification Name: Powered wheelchair

Classification: Class II.

Product code: ITI

Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device:

510(k) number: K230964

Regulation Number: 890.3860

Classification Name: Powered wheelchair

Device Name: Power Wheelchair

Zhejiang Innuovo Rehabilitation Devices Co.,Ltd

D. Indications for use of the device:

It 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.

E. Device Description:

The Electrically powered wheelchair is a motor driven, indoor and outdoor transportation vehicle, which a device for assisting action handicapped people and disabled people to move. It is suitable for disabled people with mobility difficulties and elderly people.

It is mainly composed of front wheel, drive wheel, frame,, controller (joystick), motor and drive devices, armrest, backrest, seat belt, footrest, battery box and charger.

The device is powered by Li-ion Battery pack (25V 10Ah) with 11.8 Km range, which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet(100-240V, 50/60Hz) when the device is not in use.

The user can activate the controller handle (joystick) to control the speed and direction of the wheelchair movement. When the user releases the joystick, the joystick will automatically go back to the central position and the wheelchair will be automatically stopped soon due to automatic electromagnetic brake system. Once the joystick is activated again move to other position, the wheelchair will be re-energized.

F. 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 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017, Wheelchairs - Part 2: Determination of dynamic stability of Powered Wheelchairs
- ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electric wheelchairs and wheelchairs for determination of theoretical distance range

- ISO 7176-5, Second edition 2008-06-01, 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 Powered Wheelchairs
- ISO 7176-7, 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 Powered 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, First edition 1989-08-01, 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 wheelchairs - Requirements and test methods
- ISO 7176-15:1996, Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- ISO 16840-10:2021 Wheelchair seating Part 10: Resistance to ignition of postural support devicesRequirements and test method.
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and wheelchairs, and battery chargers
- ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
- 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

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate Device

Compared to the predicate devices, the subject device has the same intended use, similar product design, similar performance, same safety as the predicate device, the summarized comparison information is listed in the following table

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K230964)	Remark
Manufacturer	Kunshan Hi-Fortune Health Products Co., Ltd	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd	--
Common or Usual name	Electrically powered wheelchair	Power Wheelchair	--
Model(s)	HP202	N5909	--
Classification	Class II	Class II	Same
Classification regulation	21 CFR890.3860	21 CFR890.3860	Same
Product code	ITI	ITI	Same

Indications for use	It 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.	It 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.	S.E.
Use condition	indoor and outdoor use	indoor and outdoor use	S.E
Number of wheels	4,including two front wheels and two rear Wheels	4,including two front wheels and two rear Wheels	S.E
Function of wheels	Front wheels:driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	Front wheels:driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	S.E
Movement control method	By Joystick control	By Joystick control	S.E
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	S.E
Brake system	Automatic electromagnetic brake system	Automatic electromagnetic brake system	S.E
Main frame material	Carbon fiber material	Carbon fiber material	S.E
Folding method	Collapsible cross-brace	Collapsible cross-brace	S.E
Braking distance	⩽1 m	⩽1.5 m	Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.
Maximum safe operational incline degree	10°	9 °	Minor difference on safe operational incline degree will not cause new safety and effectiveness concerns, as both the static and dynamic stability under specific inclining degree have been evaluated according to standard ISO 7176 series.
Armrest	Carbon fiber material	T700	Different material used for parts in

Back cushion	comfomesh	Polyester fabric	contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility tests are carried out according to ISO 10993 series.
Seat cushion	comfomesh	rubber patch cloth and Oxford fabric	
Overall Dimension (length*width*height)	1000*580*900mm	940*610*960mm	Minor difference on wheelchair dimension will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy. Analysis
Folded Dimension (length*width*height)	870*280*765mm	720*310*610mm	
Front wheel size/type	7" PU Solid tire	7" x 1.75"/PU Solid tire	S.E
Rear wheel size/type	10" PU Solid tire	8.5″x 2″/ PU Solid tire	Minor difference on dimension of wheels will not cause different performance.
Max speed forward	6 km/h (1.6 m/s)	Up to 6 km/h (1.6 m/s), adjustable	S.E
Max Speed backward	0.7 m/s (2.556 km/h)	0.71 m/s (2.556 km/h)	S.E
Max loading weight	120kg (≈265lbs)	110kg (≈250lbs)	Difference on loading weight will not cause different performance. All safety and performance have been validated with the maximum loading weight.
Battery	Li-ion battery pack; rechargeable, 24 VDC 10Ah	Li-ion battery pack; rechargeable, 24 VDC 10Ah	S.E
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Off-board charger Input:100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	S.E
Maximum distance of travel on the fully charged battery	11.8km	10 km	It is caused by the size of the wheel, will not cause different performance, The

			further away the better.
Motor	Brushless Eco-Drive, 24V,150W, 2pcs	Brushless DC motor; 24VDC; 150W; 2pcs	S.E
Electronic controller	Brushless dual-drive rocker controller	Brushless dual-drive rocker controller	S.E
Turning Radius	1000mm	900 mm	Minor difference in turning radius is caused by different size of wheelchair and may
Maximum obstacle climbing	20 mm	40 mm	Minor difference on obstacle climbing will not cause new safety and effectiveness concerns.

Substantially Equivalence Discussion:

The proposed device and predicate device are complying to the same ISO standards, ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-7, ISO 7176-8, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 16840-10, ISO 7176-21, ISO 7176-25, and FDA guidance Submission for Power Wheelchair.

The indications for use for both devices are the same. Mainframes of two devices are and the frame materials are the same carbon fiber. The design principles of the controller and Driving system are the same, and both meet the requirements of the ISO 7176-14. 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. Turning radius, 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 and ISO 7176-10. The biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2021 & ISO 10993-23: 2021.

The flame-retardant test of the seat cushion/ backrest of both subject device and predicate device is carried out according to the ISO 16840-10 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.

Table 2 Safety comparison

Item	Proposed Device	Predicate Devices	Results
Biocompatibility	All user directly contacting materials are compliance with	All user directly contacting materials are compliance with	S.E.

	ISO10993-5, ISO10993-10 and ISO 10993-23 requirements.	ISO10993-5, ISO10993-10 and ISO 10993-23 requirements.	
EMC	ISO7176-21 & IEC 60601-2-1	ISO7176-21	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Table 3 Safety comparison

Item	Proposed Device	Predicate Devices	Results
ISO7176-1	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	S.E.
ISO7176-2	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification.	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification.	S.E.
ISO7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	S.E.
ISO7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	S.E.
ISO7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5	S.E.
ISO7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-6	S.E.
ISO7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7	S.E.
ISO7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	S.E.
ISO7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	S.E.

ISO7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10	S.E.
ISO7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	S.E.
ISO7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	S.E.
ISO7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	S.E.
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	S.E.
ISO7176-16/ ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO 16840-10	S.E.
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	S.E.
ISO7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	S.E.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K230964.