November 27, 2024

Zhejiang Zhonglei Medical Technology Co. Ltd.
Ariel Xiang
Consultant
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K242308
Trade/Device Name: Power wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 30, 2024
Received: October 30, 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,

Heather L. Dean -S

Heather Dean, PhD
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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)*

K242308

Device Name

Power 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

Document Prepared Date: 2024/10//30

A. Applicant

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B. Device

Trade Name: Power wheelchair
Common Name: Powered wheelchair
Models: N6102

Regulatory Information
Classification Name: Powered Wheelchair
Classification: Class II.
Product code: ITI
Regulation Number: 890.3860

Review Panel: Physical Medicine

C. Predicate device:

510Knumber: K230964
Device Name:Power Wheelchair
Manufacturer:Zhejiang Innuovo Rehabilitation Devices Co.,Ltd

D. Indications for use of the device

The Power 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.

E. Device Description

This product consists of frame, wheels, seat, armrest, lithium battery, motor and controller with a lightweight and compact design. The whole wheelchair can be folded by one button and it can be easily carried or rolled after folding. The seat cushion is detachable. The armrest can be flipped backward, which is convenient for the elderly to move. Users can drive the wheelchair by themselves through the control device.
The wheelchair uses lithium batteries as its power source. The controller controls the drive left/right motor to realize the wheelchair forward, backward and turn functions.
The frame of the device is carbon fiber. The front wheels are driven wheels suitable for rotation, acceleration, retrograde and other actions of the wheelchair. The front wheels movement will be achieved by thrust generated from the rear wheels. The rear wheels are driving wheels to control the speed and direction. The wheels are Solid PU tires.
When in use, the operator drives the motor of the rear wheel by operating the joystick to achieve the rear wheels movement.
The DC brushless motor and brake system are fixed on the rear wheels.
The max loading of the device is 136KG. Only for one person sit.

F. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K230964)	Remark
Manufacturer	Zhejiang Zhonglei	Zhejiang Innuovo	--

	Medical Technology Co.Ltd	Rehabilitation Devices Co.,Ltd	
Common or Usual name	Power Wheelchair	Power Wheelchair	--
Model(s)	N6102	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.
Intended user	disabled or elderly person limited to a seated position.	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
Braking distance	780mm	≤1.5 m	Minor difference on braking distance will not cause different performance. Shorter distance for braking will be more safety.
Maximum safe operationalincline degree	9 °	9 °	S.E
Armrest	Carbon fibers	T700	Different material used for parts in 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.
Main frame material	Carbon fiber material	Carbon fiber material	S.E
Back cushion	Polyester fiber	Polyester fabric	S.E
Seat cushion	Polyester fiber	Polyester fiber	S.E
Overall Dimension (length*width*height)	950*610*960mm	900*580*860mm	Minor difference on wheelchair dimension will not
Folded Dimension	740*600*320mm	900*250*860mm	

(length*width*height)			cause different performance. All safety and performance have been validated with the maximum rated weight dummy. Analysis
Front wheel size/type	7" x1.78"/ PU Solid tire （180mm x45mm）	7" x 1.75"/PU Solid tire	Minor difference on dimension of wheels will not cause different performance.
Rear wheel size/type	9" x 2"/PU Solid tire （230mm x50mm）	8.5″x 1.8″/ PU Solid tire	
Max speed forward	1.54 m/s (5.5km/h)	Up to 6 km/h (1.6 m/s), adjustable	Minor difference on Max speed forward of wheels will not cause different performance.
Max loading weight	136kg (≈300lbs)	110kg (≈250lbs)	Difference on loading weight will not cause different performance. All safety and performance have been validated with the maximum loading weight.
Maximum distance of travel on the fully charged battery	16.1km	10 km	It is caused by the size of the wheel, will not cause different performance, The further away the better.

Battery	li-ion battery pack 24V,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
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	900mm	900 mm	S.E
Maximum obstacle climbing	25mm	40 mm	Minor difference on obstacle climbing will not cause new safety and effectiveness concerns.

Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 ,ISO10993-10 ,ISO10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	S.E.
EMC	ISO7176-21 and IEC 60601-1-2	ISO7176-21 and IEC 60601-1-2	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Item	Proposed Device	Predicate Device	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- 5.	The dimensions, mass has been determined after the testing according to the ISO 7176- 5.	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 testsspecified 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 ISO7176-15.	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15.	S.E.
ISO16840-10:2021	The performance of resistance to ignition meet the requirements	The performance of resistance to ignition meet the requirements	S.E.

	of ISO 16840-10:2021.	of ISO 16840-10:2021.	
ISO 7176-21/IEC60601-1-2	The EMC performance results meet the requirements of ISO IEC60601-1-2.	The EMC performance results meet the requirements of ISO 7176-21&IEC60601-1-2.	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 5and 6 of ISO 7176-25.	S.E.

G. Substantial Equivalence Discussion

The subject device complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2001, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2008, ISO7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 16840-10: 2021, ISO7176-21:2009, ISO 7176-22:2014, ISO 7176-25:2013, IEC 60601-1-2: 2014.

The intended uses for both devices are the same. Mainframes of two devices are folded by way of front and rear close.

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.

Turning radius and Maximum obstacle climbing 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 flame retardant test of the seat cushion/backrest of the subject device is conducted according to ISO 16840-10. Therefore, both devices are assured to be under the same safety level.

The all rest different between the subject device and predicate device can proved the safety or effectiveness by the ISO 7176 series support reports.

Different material used for parts in 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.

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.

H. Substantially Equivalency Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices, K230964 Power Wheelchair from Zhejiang Innuovo Rehabilitation Devices Co., Ltd.