July 1, 2022

Zhejiang Innuovo Rehabilitation Devices Co., Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K221026
Trade/Device Name: W5905 Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 6, 2022
Received: April 6, 2022

Dear Ivy 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)*
K221026

Device Name
W5905 Power Wheelchair

Indications for Use *(Describe)*
The W5905 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. 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

(As requirement by 21 CFR 807.92)

Date prepared: 21st, March, 2022

A. Applicant:

Name: Zhejiang Innuovo Rehabilitation Devices Co., Ltd.
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B. Device:

Trade Name: W5905 Power Wheelchair
Device Model: W5905

Regulatory Information
K221026
Classification Name: Wheelchair, Powered
Classification: Class II
Product code: ITI
Regulation Number: 21 CFR 890.3860
Review Panel: Physical Medicine

C. Predicate device:

K202482
Y207 Electric Wheelchair
JIANGSU INTCO MEDICAL PRODUCTS CO., LTD

D. Device Description:

The subject Power Wheelchair is a wheeled personal mobility device that incorporates a seat-support system for a person with a disability or a person without the full capacity to walk designed to be propelled by power from electric motors. The electronic control of speed and direction can be performed by the occupant with the help of controlling joystick. The device can be quickly folded and disassembled, which makes it convenient to be stored or placed at the trunk of vehicles while traveling.

The subject Power Wheelchair is intended to provide mobility to a disabled or elderly limited to a seated position. It is of indoor and outdoor type, suitable for the use indoor and flat path near buildings, but not on grass, gravel roads, large slopes or motorway, neither on muddy, rugged, soft, narrow, icy road, bad roads such as dangerous roads without guardrails or waterways.

The subject Power Wheelchair consists of two parts, the wheelchair main body and the electrical part. The main body includes a main foldable frame, two armrests, a backrest, a seat cushion, a safety belt, two rear driving wheels and two front wheels. The electrical part is composed of two motors, two brakes, a li-ion battery, a controller and an off-board charger.

The device is powered by a Li-ion battery (24V 12Ah) with 15 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 patient can activate the controller handle (joystick) to control the speed and direction of the wheelchair. The further the joystick is pushed from its central position, the faster the wheelchair moves, when it is released, it will automatically reset and brake.

E. Indication for Use

The W5905 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. This product is suitable for disabled people with mobility difficulties and elderly people.

F. Comparison of technological characteristics with the predicate device

Attribute	**Subject Device**	**Predicate Device**	**Discussion/Conclusion**
Manufacturer	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	JIANGSU INTCO MEDICAL PRODUCTS CO., LTD	/
Proprietary name, model	Power Wheelchair, W5905	Electric Wheelchair, Y207	/
Device classification	Class II	Class II	Same
Classification regulation	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same

Indications for Use	The W5905 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. 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
Intended user	Disabled or elderly person limited to a seated position	Disabled people with mobility difficulties and elderly people	Same
Use condition	Indoor and outdoor use	Indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two front wheels and two rear wheels	Same
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	Same
Frame design	The frame of the wheelchair is type capable of front and rear close. The main part of the frame can be folded for saving space and convenient storage and transportation. The main frame is made of carbon fiber.	The frame of the wheelchair is type capable of front and rear close. The main part of the frame can be folded for saving space and convenient storage and transportation. The main frame is made of high-quality aluminum material.	**Analysis:** The two wheelchairs have same frame design of front and rear close. The difference on the frame material will not cause safety and effectiveness concerns.
Movement control method	By joystick control	By joystick control	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake system	Automatic intelligent	Automatic intelligent	Same

	electromagnetic brake system	electromagnetic brake system	
Braking distance	≤1.5m	≤1.5m	Same
Battery	Li-ion battery; rechargeable, 24 VDC 12Ah	Li-ion battery pack; rechargeable, 24 VDC 20Ah	**Analysis:** Difference of battery capacity between the proposed and predicate devices may cause difference on working hours of the devices in fully charged status, which will not impact on the safe and effectiveness of the proposed device.
Maximum distance of travel on the fully charged battery	15km	20km	**Analysis:** Difference of the parameter is caused by the rated capacity of battery, which will not raise safe and effectiveness concerns.
Main frame material	Carbon fiber	Aluminum alloy	**Analysis:** Difference of the materials will not raise safe and effectiveness concerns. The biocompatibility tests have been conducted to verify the safety and effectiveness of the material.
Seat cushion	Polyester fabric	Nylon braided belt	
Armrest	Carbon fiber	PU (polyurethane)	
Overall dimension (L×W×H)	930mm×577mm×930mm	1100mm×700mm×980mm	**Analysis:** Difference on overall dimension will only affect the appearance of the device but not affect the safety and effectiveness of the subject device. All

			safety and performance have been validated with the maximum rated weight dummy or human occupant.
Folded dimension (L×W×H)	325mm×577mm×790mm	810mm×700mm×400mm	**Analysis:** Difference on folded dimension will not affect safety and performance of the subject device.
Ground clearance	70 mm	160 mm	**Analysis:** Difference on the clearance will not not affect safety and performance of the subject device. Performance tests have been conducted according to ISO 7176 series.
Front wheel size/type	7''×2''/PU solid tire	8''×2''/PU solid tire	**Analysis:** Different sizes of front wheel will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Rear wheel size/type	8''×2''/PU solid tire	10''×3''/Pneumatic tire	**Analysis:** Different sizes and materials of rear wheel will not affect the safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Max speed forward	1.7 m/s (6 km/h)	0-1.5m/s (5.4 km/h), continuously adjustable	**Analysis:** Slightly difference on the parameter will not affect the safety and performance of the subject
Max speed	0.7m/s	0.8m/s (2.88km/h)	

backward			device as all related stability tests are performed according to standard ISO 7176 series.
Minimum braking distance from maximum speed	Forward:0.8m	Forward: 1.0m	**Analysis:** Shorter braking distance in the subject device than the predicate device, all relevant tests are performed according to standard ISO 7176-3, no safety and performance will be affected.
Max loading weight	136 kg	127kg (275 lbs)	**Analysis:** Slightly difference on the parameter will not affect the safety and performance of the subject device as the related test has been performed with a dummy according to standard ISO 7176 series.
Maximum safe operational incline degree	9°	8°	**Analysis:** Slightly difference on the parameter will not affect the safety and performance of the subject device as the related test has been performed according to standard ISO 7176 series.
Battery charger	Off-board charger Input:AC 100-240V, 50/60 Hz, 1.5A Output: 24V dc, 2A Charging time: 8-10 hours	Off-board charger Input:100-240V, 50/60 Hz, 2.5A Output:24V dc, 6A; Charging time: 6 hours	**Analysis:** Current difference will impact charging time only, which will not cause new safety and effectiveness concerns raised.

Motor	Brushless DC motor 250W x 24 VDC; 2 pcs	Brushless motor; 24VDC; 200W; 2pcs	**Analysis:** Slight difference on motor power will not cause different performance. Larger power will provide more driving force, no safety and effectiveness concerns raised.
Electronic controller	35A manufactured by Shanghai Micon Mechanical & Electrical Co., Ltd.	newVSi ELECTRIC WHEELCHAIR CONTROL SYSTEM, 50A manufactured by PG DRIVES TECHNOLOGY LTD.	**Analysis:** Difference on output current will affect charging time of the subject device, which will not cause safety and effectiveness concerns.
Turning radius	1200mm	950mm	**Analysis:** Larger turning radius will bring more convenience for the use environment. All relevant tests have been performed according to standards ISO 7176 series, the difference will not raise any new safety and effectiveness concerns.
Maximum obstacle climbing	40mm	50mm	**Analysis:** Less distance in the obstacle climbing will not impact the safety and effectiveness of the subject device.

G. Summary of substantial equivalence discussion

The W5905 power wheelchair 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 7176-6:2018, 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, ISO 7176-25:2013, IEC 60601-1-2: 2014, IEC 62133-2:2017, ISO 10993-1:2018, ISO10993-5:2009, ISO 10993-10:2010.

The instructions for use, design and technological characteristics of the subject Power Wheelchair are similar to the predicate device. Mainframes of the 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 has been 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, 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 device do not raise new issues of safety or effectiveness.

H. Summary of Non-clinical Tests

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 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 7176-1:2014, Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017, Wheelchairs - Part 2 Determination of dynamic stability of electric wheelchairs
- ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4:2008 Wheelchairs - Part 4: 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.
- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25:2013Wheelchairs - Part 25: Batteries and chargers for powered wheelchair
- Risk Analysis developed in accordance with ISO 14971:2019
- Software evaluation
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014

I. Biocompatibility of Patient-contacting material

Biocompatibility of patient-contacting material are evaluated in accordance with ISO 10993-1: 2018. Although there are risks related to cytotoxicity, sensitization and irritation, the risk level is very low as the patient-contacting parts of the power wheelchair are made from materials in common use for other consumer products with a similar nature of contact, in addition, the product quality is controlled and managed by design, manufacturing, quality control, safety instructions, or warning information, hence the biological safety of the power wheelchair is acceptable without further biocompatibility testing on some parts contacted with the user during operation procedure of the product.

J. Summary of Clinical Testing

No clinical or animal study is available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the power wheelchair to its predicate device.

K. Conclusion

The differences between W5905 power wheelchair and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device power wheelchair is substantially equivalent to the legally marketed predicate device.