March 18, 2021

Jiangsu Intco Medical Products Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, No.1500, Century Ave., Pudong New District
Shanghai, Shanghai 200122
China

Re: K202482
Trade/Device Name: Y207 Electric Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 23, 2021
Received: February 25, 2021

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,

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

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)*
K202482

Device Name
Y207 Electric Wheelchair

Indications for Use *(Describe)*
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 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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K202482

510(k) Summary

Date of summary prepared: 2021/03/18

I. SUBMITTER

Name: JIANGSU INTCO MEDICAL PRODUCTS CO., LTD

Address: No.77, Yandunshan Road, Dagang, Zhenjiang, Jiangsu Province 212132, China

Name of contact person: Wang Maokun

Telephone: 0086-511-83174088

Fax: 0086-511-83174188

II. Device

Device trade name: Y207 Electric Wheelchair

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K113463, PL00l power wheelchair SUZHOU KID MEDICAL APPLIANCE CO., LTD.

IV. Device description

This electric wheelchair is a motor driven, indoor and outdoor transportation vehicle, which is a device for assisting elderly and disabled people to be mobile. It is suitable for disabled people with mobility difficulties and elderly people.

The device consists of two parts: the electrical part and the wheelchair main body. The electrical part includes motor, battery box, controller and charger. The main parts of the wheelchair include front wheels, rear wheels, frame, armrest, seat and back upholstery.

The device is powered by Li-ion Battery pack (24V 20Ah, 480Wh) with 20 Km (12.5 miles) 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 movement. In addition, when the patient releases the joystick, the joystick will return back to the central position and the wheelchair will be automatically stopped soon due to automatic intelligent electromagnetic brake system starts to work. Once the joystick is activated again move to other position, the wheelchair will be re-energized.

V. Indication for use

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.

VI. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicate device	Discussion/ Conclusion
Manufacturer	JIANGSU INTCO MEDICAL PRODUCTS CO., LTD	SUZHOU KD Medical Appliance Co. Ltd.	/
Proprietary name, model	Electric Wheelchair, Y207	power wheelchair, PLO00l	/
510(k) number	K202482	K113463	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same
Similarities			
Indication for use	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.	The device 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.	Same
Intended user	disabled people with mobility difficulties and elderly people	disabled or elderly person limited to a seated position	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 pivoting casters and two rear drive	Same

Attribute	Subject device	Predicate device	Discussion/ Conclusion
		wheels	
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	two pivoting casters: driven wheels suitable for rotation, acceleration, retrograde two rear drive wheels: driving wheels to control the speed and direction	Same
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 electromagnetic brake system	Intelligent regenerative Electromagnetic brake	Same
Braking distance	≤1.5 m	Not publicly available	Same
Battery	li-ion battery pack; rechargeable, 24 VDC 20Ah	Li-ion, Rechargeable; 24 VDC 20Ah	Same
Maximum distance of travel on the fully charged battery	20 km	20 km	Same
Main frame material	aluminum alloy	Not publicly available	Same
seat cushion	Nylon braided belt	Not publicly available	n/a
Armrest cushion	PU (polyurethane)	Not publicly available	n/a
Differences			
Overall dimensions (LxWxH)	1110 mm x 700 mm x 980 mm	Not publicly available	n/a
Folded dimensions (LxWxH)	810 mm x 700 mm x 400 mm	Not publicly available	
Ground clearance	160 mm	Not publicly available	n/a
Front wheel size/type	8" x 2"/PU Solid tire	Not publicly available	n/a
Rear wheel size/type	10″x 3″/Pneumatic tire	Not publicly available	n/a
Max speed forward	0-1.5m/s (5.4 km/h), continuously adjustable	Not publicly available	n/a
Max Speed backward	0.8m/s (2.88km/h)	Not publicly available	n/a
Minimum braking distance from maximum speed	Forward: 1.0 m	Not publicly available	n/a

Attribute	Subject device	Predicate device	Discussion/ Conclusion
Minimum braking time from maximum speed	0.7 second	Not publicly available	n/a
Max loading weight	125 kg (275 lbs)	Not publicly available	n/a
Maximum safe operational incline degree	8 °	Not publicly available	n/a
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 2.5A, Output: 24 Vdc, 6A; Charging time: 6 hours	Off-board, Automatic Type Input: 110-220 V / 50-60 Hz, Output: 24 Vdc, 2A;	Similar Output current difference will impact charging time only, which will not cause new safety and effectiveness concerns raised.
Motor	brushless motor; 24VDC; 200W; 2pcs	Brushless DC motor; 24 VDC; 180 W; 2 pcs	Similar minor difference on motor power will not cause different performance. larger power will provide more driving force, no safety and effectiveness concerns raised.
Electronic controller	newVSi ELECTRIC WHEELCHAIR CONTROL SYSTEM, 50A manufactured by PG DRIVES TECHNOLOGY LTD.	Brushless dual-drive rocker controller	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

Attribute	Subject device	Predicate device	Discussion/ Conclusion
			and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Turning Radius	950 mm	Not publicly available	n/a
Maximum obstacle climbing	50 mm	Not publicly available	n/a
thick seat cushion/ back cushion	sandwich mesh fabric (polyester)	Not publicly available	n/a

VII. Summary of substantial equivalence discussion

The Y207 INTCO electric wheelchair 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 7176-6:2001, 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, ISO 7176-25:2013, IEC 60601-1:2005+A1:2012, IEC 60601-1-2: 2014, 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.

VIII. Summary of non-clinical testing (Performance testing-bench)

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

- Risk Analysis developed in accordance with ISO 14971:2007.
- Software evaluation
- 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: 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 maneuvering space
- ISO 7176-6:2001 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 strength
- 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 - Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- ISO 7176-25:2013 Wheelchairs - Batteries and chargers for powered wheelchairs
- Electrical Safety Testing in accordance with IEC 60601-1:2005 (3rd Edition)
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014.
- 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

IX. Biocompatibility of patient-contacting material

Biocompatibility Tests are carried out in accordance with IS0 10993-1: 2018, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010). Details of the test summary see section 12 biocompatibility summary.

Component name	**Material**	**Direct contact/ indirect contact**	**Contact body**	**Contact duration**	**Evaluation tests**	**Conclusion**
Normal Seat cushion/Back cushion	Oxford fabric	Direct	intact skin surface	<24 Limited	Cytotoxicity, irritation, sensitization	TBD
Back cushion / Thick seat cushion	sandwich mesh fabric (polyester)	Direct	intact skin surface	<24 Limited	Cytotoxicity, irritation, sensitization	Pass
Handle foam tube	EVA foaming (ethylene-vinyl acetate copolymer)	Direct	intact skin surface	<24 Limited	Cytotoxicity, irritation, sensitization	TBD
Armrest cushion	PU leather (polyurethane)	Direct	intact skin surface	<24 Limited	Cytotoxicity, irritation,	TBD

					sensitization	
newVSi electric wheelchair controller						
Joystick knob	Santoprene 101-80	Direct	intact skin surface	<24 Limited	Cytotoxicity	Pass
Joystick Gaiter	Silicone 3032 (50%) & 5031 (50%)	Direct	intact skin surface	<24 Limited	Cytotoxicity	Pass
Enclosure Moulding(s)	ABS/PC Wonderloy PC-540	Direct	intact skin surface	<24 Limited	Cytotoxicity	Pass
Keypad	Silicone keypad coatings TC-2407 & CH-6330	Direct	intact skin surface	<24 Limited	Cytotoxicity	Pass

X. Summary of clinical testing

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the electric wheelchair to its predicate device.

XI. Conclusions

The differences between Y207 electric 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 Y207 INTCO electric wheelchair is substantially equivalent to the legally marketed predicate device.