May 6, 2022

Anhui JBH Medical Apparatus Co., Ltd
℅ Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, No.1500, Century Ave.
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China

Re: K212092
Trade/Device Name: Portable Folding Electric Wheelchair, Model DC01
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 5, 2022
Received: February 10, 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,

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)*
K212092

Device Name
Portable Folding Electric Wheelchair (Model: DC01)

Indications for Use *(Describe)*
The wheelchair (Model: DC01) 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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K212092 510(k) Summary

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Date prepared: 2021/06/30

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I. Device

Device trade name: Portable Folding Electric Wheelchair

Device model: DC01

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

II. Predicate device

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

III. Device description

The device is Electric Wheelchair, model no. is DC01. An electric wheelchair is a four-wheeled personal mobile device with a complementary chair support system that is powered by two motors. The traveling speed is controlled by the motor, and the traveling direction is controlled by the passenger. This product is a device suitable for disabled people with mobility difficulties and elderly people and it is intended to provide mobility to a disabled or elderly person limited to a seated position. The electric wheelchair can be travelled on flat and obstacle ground surface, and direction and speed of the wheelchair can be controlled by the passenger's hand with the help of the joystick. The device can be used to provide indoor and outdoor mobility at a certain distance but not allowed to be travelled on the road or highway.

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

The device is powered by Li-ion Battery pack (24V 6Ah, 144Wh) 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.

IV. Indication for use

The wheelchair (Model: DC01) 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.

V. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicate device	Discussion/Conclusion
Manufacturer	Anhui JBH Medical Apparatus Co., Ltd	SUZHOU KD Medical Appliance Co. Ltd.	/
Proprietary name, model	Electric Wheelchair, DC01	Power wheelchair, PL001	/
510(k) number	K212092	K113463	/
Device classification name	Class II	Class II	Same
Classification	21 CFR 890.3860	21 CFR 890.3860	Same

Attribute	Subject device	Predicate device	Discussion/Conclusion
regulations			
Product code	ITI	ITI	Same
Similarities			
Intended user	disabled people and elderly people	disabled or elderly person	Same
Indication for use	The wheelchair (Model: DC01) 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.	They are 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
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 wheels	Same
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	Smart Electromagnetic brake	Intelligent regenerative Electromagnetic brake	Same
Electronic controller	Dual Drive Controller for Brushless Motor	Brushless dual-drive rocker controller	Same
Motor	Brushless DC motor 180W x 24 VDC x 2 pcs	Brushless DC motor; 24 VDC; 180 W; 2 pcs	Same
Armrest	PU	PU	Same
Max speed forward	3.75 mph (6 km/h)	Up to 6 km/h (3.75 mph), variable	same
Maximum distance of travel on the fully charged battery	20 km	20 km	Same
Turning Radius	800 mm	31.5” (800 mm)	Same
Differences			
Frame design and material	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 material.	The frame of the wheelchair is type of aluminum frame with front and rear folding structure; Up-and-down turnable handrail, front and rear adjustable armrest. The main frame is made of aluminum alloy material.	both of the wheelchair can be folded in the way of front and rear folding type.
Minimum braking distance from	Forward: 0.5 m	Forward:1.5 m	shorter braking distance in the subject device than the

Attribute	Subject device	Predicate device	Discussion/Conclusion
maximum speed			predicate device, all relevant tests are performed according to standard ISO 7176-3, no safety and performance will be affected.
Battery	Lithium-ion, 24V6Ah, 6Ah x 24 VDC	Li-ion, Rechargeable; 24 VDC 20Ah	Same rated voltage, as for difference on power capacity, both batteries are tested according to standard IEC 62133-2, no differences of batteries between both devices will affect the safety and performance of the subject device.
Battery charger	Off-board charger Input: 100-240Vac, 50/60Hz, 1.5 A; output: DC 24V, 2A,	Off-board, Automatic Type Input: 110-220 V / 50-60 Hz, Output: 24 Vdc, 2A	More wide range of input voltage in the device which will not cause new safety and effectiveness concerns raised.
seat cushion/back cushion	linen cloth filled with PU foam	PU foam covered by nylon fabric cloth	Different surface material in contact with the driver, the biocompatibility evaluation is performed on both devices, such difference will not affect the safety and performance of the subject device
Maximum safe operational incline degree	8 °	9 °	Minor difference on safe operational incline degree will not cause new safety and effectiveness concerns are raised as both the static and dynamic stability under specific inclining degree have been evaluated according to standard ISO 7176 series.
Max loading weight	120 kg (264 lbs)	114 kg (251 lbs)	Minor difference on loading weight will not cause different performance as all performance tests are performed according to standard ISO 7176 series
Front wheel size/type	7" x 1.75" /PU Solid tire	6″x 2″/PU Solid tire	different size of driven wheel will not affect safety and performance of the subject device as all related stability tests are performed

Attribute	Subject device	Predicate device	Discussion/Conclusion
			according to standard ISO 7176 series.
Rear wheel size/type	8”x1.95" /PU solid tires	8" x 2.4"/PU Solid tire	different size of driving wheel will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Maximum obstacle climbing	20 mm	1.2” (30 mm)	less distance in the obstacle climbing will not impact the safety and effectiveness of the subject device.

VI. Summary of substantial equivalence discussion

The DC01 electric 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, ISO 10993-1:2018, ISO10993-5:2009, ISO 10993-10:2010.

The intended uses for both devices are totally same. Mainframes of two devices are folded by way of front and rear close, although the locking structure for both devices are different from each other, the folding principle is the same. As for different frame materials used and minor difference on safe operational incline degree for both devices, considering all safety and performance tests are carried out on the subject device with favorable result, such difference will not affect the safety and performance of the subject device. 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 speed 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 7176-2:2017, ISO 7176-10:2008. The biocompatibility of the subject device is evaluated according to standard ISO 10993-1 and meet the requirements accordingly.

All seat cushion/back cushion and armrest are made of flame retardant material for both devices.

Therefore, the subject device is 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 device do not raise new issues of safety or effectiveness.

VII. 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 14971:2019.
- 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 7176-6:2018 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 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 7176-21:2009 Wheelchairs - Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- 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

VIII. Biocompatibility of patient-contacting material

Biocompatibility of patient-contacting material are evaluated in accordance with lS0 10993-1: 2018. All parts of the wheelchair surface in contact with user skin are patient contact parts for the electric wheelchair. The biocompatibility tests are carried out on patient-contact materials, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010) and irritation (ISO 10993-10:2010). The test results show all materials used are bio-safe. Below is the summary table:

Component name	Material	Direct contact/ indirect contact	Contact body	Contact duration	Evaluation tests
Seat cushion (surface)	linen cloth	Direct	intact skin surface	<24 Limited	Cytotoxicity Sensitization Irritation
Back cushion (surface)					
Armrest	PU (polyurethane)				
Frame	carbon fiber	Direct	intact skin surface	<24 Limited	Cytotoxicity Sensitization Irritation
controller surface	plastic part	Direct	intact skin surface	<24 Limited	Cytotoxicity Sensitization Irritation
Joystick	plastic part	Direct	intact skin surface	<24 Limited	

IX. 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.

X. Conclusions

The differences between DC01 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 the subject device electric wheelchair DC01 is substantially equivalent to the legally marketed predicate device.