5. 510(k) Summary of Safety and Effectiveness

(per 21 CFR 807.92)

Submitter's Name:	***Nanjing Jin Bai He Medical Apparatus Co., Ltd.*** No. 61 Qinhuai Road, Jiangning Economic and Technological Development Zone, Nanjing, Jiangsu, China 211106
Date summary prepared:	July 5, 2017
Proprietary Name:	Powered Wheelchair, DYW30A(D09)
Common or Usual Name:	Powered Wheelchair
Classification Name	Powered Wheelchair, Class II, 21 CFR 890.3860
Product Code:	ITI
Company contact person:	Dr. KE-MIN JEN (Email: ceirs.jen@msa.hinet.net) TEL: +886-3-5208829, FAX:+886-3-5209783
Predicate Device	SUZHOU KD MEDICAL APPLIANCE CO. LTD. PL00l power wheelchair K113463

- **Indications for Use**:

The device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.

- **Device Description:**

The powered wheelchair DYW30A(D09) is driven by two DC motors, and is suitable for indoor uses. It is an individual transportation vehicle for disabled and elderly people that experience difficulties in walking. The powered wheelchair DYW30A(D09) comes as preassembled, designed to be lightweight, easily maneuvered, highly portable, and most importantly, safe and comfortable.

It consists of two foldable armrests, a seat belt, a backrest, a seat cushion, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, two Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.

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The device is powered by two 12 volt / 6 Ah Lithium-ion batteries with 11.2 miles travel range that can be recharged by an off-board battery charger that can be plugged into an AC outlet (110-220 V, 50-60 Hz), when the device is not in use.

The user can activate the joystick to move in the direction of the joystick is actuated. When the user releases the joystick, the device slows to stop and the brakes are automatically re-engaged. The maximum weight capacity of DYW30A(D09) is **264 lbs** and its maximum speed is **3.75 mph**.

The following surfaces are recommended **NOT** to operate on:

- Sand surface
- Wet or icy surface
- Road maintenance hole metal cover
- Do not use on stairs
- Do not use escalators. Use the elevator.
- Too steep incline over **8** degrees.
- Obstacle climbing ability: **1.36”**
- Do not use outdoors

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- **Performance Testing**:

✓ ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability

✓ ISO 7176-2:2001 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs

✓ ISO 7176-3:2013 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.

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- ✓ 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
- ✓ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ✓ IEC 62133:2012 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

- **Biocompatibility of patient-contacting material**

Patient-contacting parts	Materials	Rational for biocompatibility testing	Conclusion
Seat Backrest Safety belt Joystick	PVC Vinyl	*ISO 10993-1:2009 *PVC Vinyl material is adopted by many wheelchair manufacturers in the market, and it is common and mature material for wheelchair parts. *No customer claim with adverse conditions for more than thousands of units sold in the market.	We conduct the ISO 10993-5 and ISO 10993-10 tests.
Armrest	PU Foam	*ISO 10993-1:2009 *PU Foam material is adopted by many wheelchair manufacturers in the market, and it is common and mature material for wheelchair parts. *No customer claim with adverse conditions for more than thousands of units sold in the market.	We conduct the ISO 10993-5 and ISO 10993-10 .tests.

- **Comparison table**

Devices / Specifications	**Predicate device**	**Subject device**	**Explaining no new safety and effectiveness concerns raised due to the differences**
Manufacturer	Suzhou KD Medical Apparatus Co., Ltd.	Nanjing Jin Bai He Medical Apparatus Co., Ltd.	Devices made by different manufacturers
Proprietary name	Power Wheelchair	Powered Wheelchair,	Different devices
Model name	PL001	DYW30A(D09)	Different models
510(k) No.	K113463	K170787	New 510(k) submission
Similarities			
Indications for use	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	The device is a motor-driven, and **indoor** transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.	The PL001 is for indoor and outdoor uses and the DYW30A(D09) is for indoor use. The restriction in indoor use can decrease the risk level for the subject device, thus ensure no new safety and effectiveness concerns raised due to the difference.
Motor	Chongqing Mao Tian Machinery Co., Ltd., Brushless DC motor 180 W×24 VDC×2 pcs	Chongqing Mao Tian Machinery Co., Ltd., Brushless DC motor 250W x 24 VDC x 2 pcs	Similar motors are made by the same company. Our motor power is larger than predicate device, and this means more driving force are supplied to the subject device, no safety and effectiveness concerns raised.
Battery	Jiangsu Feng Chi Green Power Supply Co., Ltd., Lithium-ion 10Ah×24 VDC×2 pcs	Jiangsu Feng Chi Green Power Supply Co., Ltd., Lithium-ion, ITP2406 6 Ah x 24 VDC x 2 pcs	Similar batteries are made by the same manufacturer. Our battery meets ISO

			7176-25:2013, and no new safety and effectiveness concerns raised.
Charger model & rating	High Power Technology Inc. HP1202B Input: AC100-240V Output: DC 24V, 2Amp	High Power Technology Inc. HP0060W(L2) Input: 100-240 VAC Output: DC 24V, 2 Amp	Similar chargers are made by the same manufacturer. Our charger meets ISO 7176-25:2013, and no new safety and effectiveness concerns raised.
Number of Wheels	4	4	Same number of wheels
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same driving system
Brake System	Smart Electromagnetic brake	Smart Electromagnetic brake	Same brake system
Max Speed (Forwards)	3.75 mph (6 km/h)	3.75 mph (6 km/h)	Same maximum speed, forward
Speed control method	Joystick control method	Joystick control method	Same speed control method
Main frame material	6063 aluminum alloy	6063 aluminum alloy	Same frame material
Differences			
Use environments	Indoor and outdoor use	Indoor use	Restricted use in the indoor environment will ensure lower risk level.
Front wheel size & type	6” x 2” (150×38 mm) (PU Solid tire)	7”x1.77” (180 x 45 mm) (PU solid tire)	Larger sizes of front wheels bring steadier pivoting function than predicate device.
Rear wheel size & type	8” x 2” (200 x 50 mm) (PU solid tire)	12.5” x 2.25” (320 x 57 mm) (PU solid tire)	Larger sizes of rear wheels bring more comfortable ride feeling than predicate device.
Maximum safe operational incline	12 degrees	8 degrees	We restrict the use environment for the subject device to be indoor. Safe operational

			incline of 8 degrees for the DYW30A(D09) is enough for indoor use. No new safety and effectiveness concerns are raised by this difference.
Dimensions (LxWxH)	38.2” × 23.2” × 33.1”	37.4” x 22.6” x 36.2”	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Weight, w/ Battery	60.87 lbs. / 27.6 kg	51.8” lbs. / 23.5 kg	Less weight will lead to more convenience when transported and there is more cruising range than predicate device.
Cruising Range	9.3 miles (15 km)	11.2 miles (18 km)	This difference is due to the less weight and more power for the subject device, based on the work and energy theorem. There is a larger cruising range for the subject device.
Max Loading	250 lbs.	264 lbs.	More loading weight means more convenient for the transportation.
Max Speed Backward	2.4 mph (3.84 km/h)	1.86 mph (3.0 km/h)	Smaller backward speed means lower risk level for the subject device.
Turning Radius	31.5” (800 mm)	32.5” (833 mm)	The minor difference in the turning radius will cause some inconvenience when it turns in a narrow space and the difference will not raise any new safety and effectiveness concerns.

Maximum obstacle climbing	1.2” (30 mm)	1.36” (34.5 mm)	The larger height in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Controller	Brushless dual-drive rocker controller	Changzhou Billon Electronic Appliance Co., Ltd., WS-1	Our controller passed ISO 7176-14 and there is no safety and effectiveness concerns raised due to this difference.
Minimum braking distance	1.5 m	1 m	Our minimum braking distance is smaller than the predicate device and this ensures more safety. There is no new safety and effectiveness concerns raised due to the difference.

- **Substantial equivalent discussion**

Firstly please refer to the explanations in the comparison table. The engineering design and technical properties of DYW30A(D09) powered wheelchair are very similar to the predicate device, PL001 power wheelchair. Both chairs utilize **dual brushless motors** as their power sources, and the motors are manufactured by the same company, while PL001 uses 180W motors, DYW30A(D09) uses 250W motors.

The Lithium-ion **batteries** used by both powered wheelchairs come from the same manufacturer as well, though PL001 power wheelchair uses 10Ah batteries and DYW30A(D09) powered wheelchair uses 6Ah batteries. The maximum speed of DYW30A(D09) is the same as the predicate device.

The **control system**, including the joystick controller, the smart electromagnetic brakes and their user interface are similar. The joystick controls the directions of the powered wheelchair, move the joystick in the direction that the user is looking to go, and when the joystick is released, the powered wheelchair will come to a stop slowly, and the brakes will automatically re-engage. The control system of the subject device passed the ISO 7176-14:2008 and there are no new safety and effectiveness concerns due to the difference.

The **turning radius** of the subject device is larger than that of the predicate device by 1.0”. This difference will bring slight inconvenience to the user of the subject device while doing a turning in the limited space, but this is not related to the safety aspect.

Other minor differences between two powered wheelchairs include **weights**, overall **dimensions** and maximum **weight capacity,** and these do not change the overall functions and intended uses of the DYW30A(D09).

DYW30A(D09) has passed the relevant testing, including **ISO 7176 series** and **IEC 60601-1-2:2014,** to ensure there are no new safety and effectiveness concerns when compared with the predicate device.

Predicate device:
PL001 power wheelchair

Side view

Subject device:
DYW30A(D09) powered wheelchair

- **CONCLUSIONS**

The subject device, DYW30A(D09), is as safe and effective as, and functions in a manner equivalent to the predicate device, PL001 (K113463). The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate device.