DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 5, 2017

Kunshan Aoshida Electric Technology Co., Ltd
% Mrs. Junnata Chang
Official Correspondent
IRC China
16f-2(16a), No. 462, Sec. 2, Chongde Rd., Beitun Dist.
Taichung, 406 TW

Re: K163204
Trade/Device Name: A08 Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 30, 2017
Received: April 13, 2017

Dear Mrs. Junnata Chang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163204

Device Name
A08 Power Wheelchair

Indications for Use *(Describe)*
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.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Applicant

Name: Kunshan Aoshida Electric Technology Co., Ltd
Address: No. 65, Matang Road, Kunshan City, Jiangsu Province, 215333, China
Contact person: Shen Wenhua
Phone: +86-512-57816288
Fax: +86-512-57816388

Date prepared: Jan. 20, 2017

Device identification

- Trade name : A08 power wheelchair
- Common name: Powered wheelchair
- Classification name: Powered wheelchair
- Medical specialty (Panel): Physical Medicine Device
- Regulation number: 890.3860
- Product code: ITI
- Classification: Class II

Predicate devices

Trade name: PL001 power wheelchair
510(k) number: K113463
Manufacture: SUZHOU KD MEDICAL APPLIANCE CO. LTD.
Regulation number: 890.3860
Product Code: ITI
Classification: Class II

Intend use of device

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.

Device description:

The A08 power wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The design of this wheelchair is basically similar to other powered wheelchairs that are already on the market.

The A08 power wheelchair is with a 100 kg (220 lbs) weight capacity. It is basic

conventional rear wheels drive, rigid frame vehicle that are battery powered. It consists primarily of a foldable welded-aluminum frames, two sealed transaxle motors (250 W, DC 24V) drive system, electromagnetic braking system, electric motor controller (Yisheng Electric Co., Ltd., Model: WS-1) and two Li-ion batteries with an off-board battery charger (2 A). It is powered by two 12 volt Li-ion DC batteries with 20 km (12.5 miles) with 20 Ah which maximum speed upto 7 km/hr (4.4 mph). The controller with a joystick attaches to either armrest and allows the rider to control the movement and velocity of the powered wheelchair. When the joystick is released, the electromagnetic brake will be actuated and the power wheelchair is slow to stop.

Summary of non-clinical testing

The A08 power wheelchair complied with the requirements of the ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-7, ISO 7176-8, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 7176-16, ISO 7176-21, ISO 7176-25, ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 14971 and IEC 62133.

Statement of substantial equivalence

The A08 power wheelchair is substantially equivalent to the PL001 (K113463) manufactured by SUZHOU KD MEDICAL APPLIANCE CO. LTD.. They have same intended use of a motor driven, indoor and outdoor transportation vehicle to provide mobility to a disabled or elderly person limited to a seated position.

The design and technological characteristics of this device is basically similar to the predicate device. They are 4-wheeled power wheelchair with basic conventional rear wheel drive which with free-wheel mode. The motor of both devices is equipped with differential mechanism. The anti-tip wheels are equipped behind the rigid frame of both devices. The power supply of both devices is Li-ion batteries to provide power that can be recharged by an off-board charger that can be plugged into an AC outlet when the devices are not in use. The horn is also equipped on both devices. Both devices have the same user interface, the patient uses the joystick to engage and disengage the power wheelchair motion in both the forward and reverse directions. When the joystick is released, the electromagnetic brake will be actuated and the power wheelchair is slow to stop.

Both seats of the devices are equipped with removable flip-up armrest and there is no headrest on backrest. Seat cushions and backrests of both devices used the same materials, which is PU foam covered by nylon fabric cloth. The seat, seat cushion, backrest, joystick of the device will contact to the patient. The materials of the patient contacting parts used for the A08 power wheelchair and predicate device are exactly

same and no additional processing different from predicate device, so no new safety and efficacy concerning.

The main difference for the two devices is the rated power of the motor, maximum curb height and the maximum speed. While there are minor differences between the devices including max load capacity, dimension, wheels size, braking distance and pre-charging distance, do not alter the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Kunshan Aoshida Electric Technology Co., Ltd concludes that, A08 power wheelchair is substantially equivalent to predicate devices as described herein.

The substantial equivalence comparison of the A08 and PL001 (K113463)

	PL001 (K113463)	A08	Comparison to the predicate device
Indications for use	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 indications for use
Maximum load capacity	114 kg (251 1bs)	100 kg (220 lbs)	Smaller load capacity
Overall length	900 mm (35.4")	890 mm (35")	Smaller overall length
Overall width	600 mm (23.6")	603 mm (23.7")	Larger overall width
Stowage length	106 cm(41.7")	324 mm(12.8")	Larger stowage length
Stowage width	510 mm(20.1")	603 mm(23.7")	Larger stowage width
Stowage height	450 mm(17.7")	670 mm(26.4")	Larger stowage height
Rising	150 mm(5.9")	40 mm(1.57")	Smaller rising
Total mass:	with battery : 26 kg (57.2 lbs) without battery : 23 kg(50.6 lbs)	with battery : 28 kg(61.7 lbs) without battery : 24 kg(53 lbs)	Heavier mass
Mass of heaviest part	23 kg (50.6 lbs) body frame with motor	24 kg(53 lbs) body frame with motor	Heavier mass of heaviest part
Pivot width	250 cm(98.4")	150.5 cm(59.3")	Smaller pivot width
Reversing width	160 cm(63")	233 cm(91.7")	Larger reversing width
Turning diameter	160 cm(63")		Same turning diameter
Ground clearance	60 mm(2.4")	63.5 mm(2.5")	Larger ground clearance
Required width of angled corridor	120 cm(47.2")	100 cm(39.4")	Smaller required width of angled corridor
Required doorway entry depth	106 cm(41.7")	160 cm(63")	Larger required doorway entry depth
Required corridor width for side opening	190 cm(74.8")	120 cm(47.2")	Smaller required corridor width for side opening

(Continuous) The substantial equivalence comparison of the A08 and PL001 (K113463)

	PL001 (K113463)	A08	Comparison to the predicate device
Seat plane angle	5°	2°	Smaller seat plane angle
Effective seat depth	350 mm(13.8")	430 mm (17")	Larger effective seat depth
Seat width	350 mm(13.8")	450 mm (17.7")	Larger seat width
Effective seat width	307 mm ~ 430 mm(12" ~ 17")	450 mm(17.7")	Larger effective seat width
Seat surface height at front edge	440 mm~516 mm(17.3"~20.3")	470 mm(18.5")	Larger seat surface height at front edge
Back support angle	12°	20°	Larger back support angle
Back support height	395 mm(15.6")	470 mm(18.5")	Smaller back support height
Back support width	350 mm(13.8")	440 mm (17.3")	Larger back support width
Foot support to seat distance	345 ~ 421 mm(13.6" ~ 16.6")	400 mm(15.7")	Predicate device is adjustable
Foot support clearance	70 mm(2.8")	55 mm(2.2")	Smaller foot support clearance
Arm support height	155 mm(6.1")	200 mm(7.9")	Larger arm support height
Front of arm support to back support	250 mm(9.8")	350 mm(13.8")	Larger front of arm support to back support
Arm support length	260 mm(10.2")	335 mm(13.2")	Larger arm support length
Arm support width	50 mm(2")		Same arm support width
Arm support angle	0°	12°	Larger arm support angle
Distance between arm supports	420 mm(16.5")	480 mm(18.9")	Larger distance
Horizontal location of the wheel axle	219 mm(8.6")	120 mm(4.7")	Smaller horizontal location of the wheel axle
Vertical location of the wheel axle	284 mm(11.2")	320 mm(12.6")	Larger vertical location of the wheel axle
Caster wheel diameter	200 mm(8")	176 mm(7")	Smaller diameter

(Continuous) The substantial equivalence comparison of the A08 and PL001 (K113463)

	PL001 (K113463)	A08	Comparison to the predicate device
Material	PU foam covered by nylon fabric cloth		Same material
Seat			
Seat cushion			
Backrest			
Differential mechanism	Differential rate: 22 : 1		Same differential rate
Free-wheel mode	Yes		Both devices have free- wheel mode
Lights			Both devices do not have lights
Head/Tail lights	No		
Signal light	No		
Warning light	No		
Horn	Yes		Both devices have horn
Anti-tip wheels	Yes		Both devices have anti-tip wheels
Armrest	Removable flip-up armrest		Both devices have adjustable armrest
Headrest	No		Both devices do not have headrest
Motor			
Rated power	150 W	250 W	Larger rated power
Input voltage	DC 24V		Same input voltage
Amount	2 Pcs		Same amount
Brake system	Intelligent regenerative electromagnetic brake		Same brake system

(Continuous) The substantial equivalence comparison of the A08 and PL001 (K113463)

	PL001 (K113463)	A08	Comparison to the predicate device
Controller	Yisheng Electric Co. Ltd , WS-1, 40A		Same controller
Rear wheel drive	Sealed transaxle direct drive		Same drive mode
Braking distance	Forward:1.5 m (59") at max speed	Forward: 1 m (39.4") at max speed	Smaller braking distance
Per-charge distance	Up to 20 km (12.5 miles)		Same pre-charging distance
Maximum speed	Up to 6 km/h (3.75 mph) , variable	Up to 7 km/hr (4.4 mph), variable	Larger max. speed
Maximum curb height	30 mm (1.2")	40 mm(1.57")	Larger curb height
Battery			
Type	Li-ion, Rechargeable		Same type
Rated power	20 Ah		Same rated power
Output voltage	24 VDC		Same output voltage
Amount	DC 12V x 2 Pcs		Same amount
Battery level indicator	Yes		Both devices have battery level indicator
Charger			
Type	off-board, Automatic Type		Same type
Main plug	Standard US-plug, 2 pins		Same type
Input power requirement	110-220 V / 50-60 Hz		Same input power requirement
Output voltage / current	DC 24V / 2A		Same output voltage / current

(Continuous) The substantial equivalence comparison of the A08 and PL001 (K113463)

	PL001 (K113463)	A08	Comparison to the predicate device
Front wheels			
Diameter	8" × 2"	7" × 2"	Smaller diameter
type	non-pneumatic tires		Same type
Material	Polyurethane (PU)		Same materials
Amount	2		Same amount
Rear wheels			
Diameter	8" × 2.4"	10" × 2.35"	Larger diameter
type	non-pneumatic tires		Same type
Material	Polyurethane (PU)		Same materials
Amount	2		Same amount