October 7, 2022

Tung Keng Enterprise Co., Ltd.
℅ Jen Ke-Min
Contact Person
Roc Chinese-European Industrial Research Society
No. 58, Fu Chiun Street
Hsin Chu, Taiwan 30067
Taiwan

Re: K220156
Trade/Device Name: Electrically Powered Wheelchair, Joy Rider
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 30, 2022
Received: September 7, 2022

Dear Jen Ke-Min:

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,

Tushar Bansal, PhD
Acting 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)*

Device Name

Indications for Use *(Describe)*

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TUNG KENG ENTERPRISE CO., LTD.
No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist.,
Taichung City, Taiwan
Tel: +886-4-25321000 Fax: +886-4-25325000
Website: www.dkcity.com

510(k) Summary (per 21 CFR 807.92)

510(k) number: K220156

Submitter's Name:	Tung Keng Enterprise Co., Ltd.
Date summary prepared:	October 6, 2022
Trade Name:	Joy Rider
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
Predicate Device	Manufacturer: Nanjing Jin Bai He Medical Apparatus Co., Ltd. Device name: Powered Wheelchair, DYW30A(D09) 510(k) number: K170787

- **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.

- **Intended User Population**:

The target population of the device is Adults only. (FDA defines 'an adult' as anyone over the age of 22 years.)

- **Device Description:**

The TUNG KENG Electrically Powered Wheelchair, Joy Rider, is suitable for indoor uses. It is characterized by high portability in comfortable travel, small storage and convenient delivery in daily life. As folding of Joy Rider only takes just a few seconds, so this model increases opportunities for travel and provides small storage. To use Joy Rider makes your travel in any place and at any moment! It is an individual transportation vehicle for disabled and elderly people that experience difficulties in walking. The Joy Rider comes as preassembled, designed to be lightweight, easily maneuvered, highly portable, and most importantly, safe and comfortable.
It is driven by two brushless DC motors, and contains two foldable armrests, a seat belt, a

backrest, a seat cushion and small with light texture, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, one Lithium-ion battery, an off-board battery charger, a control panel, and an electrical controller.

The device is powered by one 24 VDC/ 10.5 Ah Lithium-ion battery with 9.3 miles cruising range that can be recharged by an off-board battery charger, rated at input: 100-240 VAC / 50-60 Hz, and output: 24 VDC/ 2 A, that can be plugged into an AC outlet, when the device is not in use. Its overall dimensions are 33.6" x 22.6" x 35.8" (855 x 580 x 910 mm). 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 Joy Rider is 264 lbs. (120 kg) and its maximum speed is 3.75 mph (6 km/h).

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

- Sand surface
- Wet or icy surface
- Road maintenance hole metal cover
- Avoid going up multiple steps.
- Avoid using escalators. Use the elevator.
- Too steep incline over **10** degrees.
- Obstacle climbing ability: **1.96" (50 mm)**

- **Non-clinical performance tests**
  - ANSI/RESNA WC-1:2019 Requirements and test methods for wheelchairs (including scooters)
  - ANSI/RESNA WC-2: 2019 Additional requirements for wheelchairs (including scooters) with electrical systems
  - ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability, (FDA Recognition Number: 16-195)
  - ISO 7176-2:2001 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs, (FDA Recognition Number: 16-202)
  - ISO 7176-3:2013 Wheelchairs - Part 3: Determination of effectiveness of brakes, (FDA Recognition Number: 16-192)
  - ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range, (FDA Recognition Number: 16-162)
  - ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering space, (FDA Recognition Number: 16-163)

- ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs,
(FDA Recognition Number: 16-204)
- ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, (FDA Recognition Number: 16-196)
- ISO 7176-8:2014 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strength, (FDA Recognition Number: 16-197)
- ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchair, (FDA Recognition Number: 16-167)
- ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs, (FDA Recognition Number: 16-164)
- ISO 7176-11:2012 Wheelchairs — Part 11: Test dummies,
(FDA Recognition Number: 16-190)
- ISO 7176-13: 1989 Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces, (FDA Recognition Number: 16-25)
- ISO 7176-14:2008 Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods, (FDA Recognition Number: 16-165)
- ISO 7176-15:1996 Wheelchairs -- Part 15: Requirements for information disclosure, documentation and labeling, (FDA Recognition Number: 16-27)
- ISO 7176-16:2012 Wheelchairs — Part 16: Resistance to ignition of postural support devices, (FDA Recognition Number: 16-191)
- ISO 7176-21:2009 Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, (FDA Recognition Number: 16-166)
- ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures,
(FDA Recognition Number: 16-198)
- ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, (FDA Recognition Number: 2-245)
- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization, (FDA Recognition Number: 2-174)
- IEC 60601-1:2005 Medical electrical equipment - Part 1 General requirements for basic safety and essential performance, (FDA Recognition Number: 19-4)
- 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,
(FDA Recognition Number: 19-8)
- 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.
(FDA Recognition Number: 19-13)

TUNG KENG ENTERPRISE CO., LTD.
No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist.,
Taichung City, Taiwan
Tel: +886-4-25321000 Fax: +886-4-25325000
Website: www.dkcity.com

- **Biocompatibility of patient-contacting parts**

Patient-contacting Parts	Material's name	Contact classification & contact duration	Tests conducted	Rational for the tests conducted	Corresponding test reports
1. Seat cover Backrest Seat belt	Vinyl Fabric	Surface contacting- Less than 24 hours duration	Cytotoxicity Sensitization + Skin Irritation testing	Per ISO 10993-1:2009	*Vinyl Fabric ISO 10993-5 (Cytotoxicity Test)_Joy rider *Vinyl Fabric ISO 10993-10 (Maximization Sensitization Test)_Joy rider *Vinyl Fabric ISO 10993-10 (Skin Irritation Test)_Joy rider
2. Armrest	PU Foam	Surface contacting- Less than 24 hours duration	Cytotoxicity + Maximization Sensitization + Skin Irritation testing	Per ISO 10993-1:2009	*PU Foam ISO 10993-5 (Cytotoxicity Test)_Joy rider *PU Foam ISO 10993-10 (Maximization Sensitization Test)_Joy rider *PU Foam ISO 10993-10 (Skin Irritation Test)_Joy rider
3. Joystick	TPU	Surface contacting- Less than 24 hours duration	Cytotoxicity + Maximization Sensitization + Skin Irritation testing	Per ISO 10993-1:2009	*TPU Joystick ISO-10993-5 in vitro Cytotoxicity TEST_Joy rider *TPU Joystick ISO-10993-10 Maximization Sensitization TEST_Joy tider *TPU Joystick ISO-10993-10 Skin Irritation TEST_Joy rider

TUNG KENG ENTERPRISE CO., LTD.
No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist.,
Taichung City, Taiwan
Tel: +886-4-25321000 Fax: +886-4-25325000
Website: www.dkcity.com

- **Comparison table**

Devices / Specifications	**Subject device**	**Predicate device**	**Comparison analysis**
Manufacturer	Tung Keng Enterprise Co., Ltd.	Nanjing Jin Bai He Medical Apparatus Co., Ltd.	--
Proprietary name	Electrically Powered Wheelchair	Powered Wheelchair,	--
Model name	Joy Rider	DYW30A(D09)	--
510(k) No.	K220156	K170787	--
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.	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.	Same
Intended user population	The target population of the device is Adults only. (FDA defines 'an adult' as anyone over the age of 22 years.)	The target population of the device is Adults only. (FDA defines 'an adult' as anyone over the age of 22 years.)	Same
Motor	LINIX, 120ZWN24-200, Brushless DC motor 200 W x 24 VDC x 2 pcs Electromagnetic brake	Chongqing Mao Tian Machinery, Brushless DC motor 250W x 24 VDC x 2 pcs	Different
Battery	TOP Best Energy Storage Corp. Lithium-ion battery 10.5 Ah x 24 VDC x 1 pcs	Jiangsu Feng Chi Green Power Supply Co., Ltd., Lithium-ion, ITP2406 6 Ah x 24 VDC x 2 pcs	Similar
Charger model & rating	High Power Technology HP0060W(L2) Input: 100-240 VAC, 50/60 Hz Output: 24 VDC, 2 Amp	High Power Technology HP0060W(L2) Input: 100-240 VAC, 50/60 Hz Output: 24VDC, 2 Amp	Same
Number of Wheels	4	4	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake System	Electromagnetic brake	Smart Electromagnetic brake	Same
Max Speed	3.75 mph (6 km/h)	3.75 mph (6 km/h)	Same

TUNG KENG ENTERPRISE CO., LTD.
No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist.,
Taichung City, Taiwan
Tel: +886-4-25321000 Fax: +886-4-25325000
Website: www.dkcity.com

(Forwards)			
Speed control method	Joystick control method	Joystick control method	Same
Main frame material	6063 aluminum alloy	6063 aluminum alloy	Same
Use environments	Indoor use	Indoor use	Same
Front wheel size & type	7” x 1.77” (180×45 mm) (PU Solid tire)	7” x 1.77” (180 x 45 mm) (PU solid tire)	Same
Rear wheel size & type	10” x 2.25” (254 x 57 mm) (PU solid tire)	12.5” x 2.25” (320 x 57 mm) (PU solid tire)	Different
Maximum safe operational incline	10 degrees	8 degrees	Different
Dimensions unfolded (LxWxH)	33.6” x 22.6” x 35.8” (855 x 580 x 910 mm)	37.4” x 22.6” x 36.2” (960 x 580 x 930 mm)	Different
Dimensions folded (LxWxH)	43.8” x 22.8” x 12.5” (1115 x 580 x 320 mm)	22.6”* 12.6”* 30.4” (580 * 325 *780 mm)	Different
Weight, without battery	49.8 lbs. / 22.6 kg	51.8” lbs. / 23.9kg	Similar
Cruising Range	9.3 miles (15 km)	11.2 miles (18 km)	Different
Max Loading	264 lbs. (120 kg)	264 lbs.(120 kg)	Same
Max Speed backward	2.4 mph (3.84 km/h)	1.86 mph (3.0 km/h)	Different
Turning Radius	33.5” (850 mm)	32.5” (833 mm)	Similar
Maximum obstacle climbing	1.96” (50 mm)	1.36” (34.5 mm)	Different
Controller	PG nVR2 BLDC, Brushless double drive joystick controller	Changzhou Billon Electronic Appliance Co., Ltd., WS-1	Different
Minimum braking distance	1 m	1 m	Same

TUNG KENG ENTERPRISE CO., LTD.
No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist.,
Taichung City, Taiwan
Tel: +886-4-25321000 Fax: +886-4-25325000
Website: www.dkcity.com

- **Substantial Equivalence discussion**

We will not discuss the same or similar items in the substantial equivalent discussion. We will discuss the different items: motor used, Rear wheel size & type, Maximum safe operational incline, Dimensions unfolded (L x W x H), Dimensions folded (L x W x H), Travel range, Max speed backward, Maximum obstacle climbing, and Controller.

The predicate device uses 2 pieces of Chongqing Mao Tian Machinery, Brushless DC motor (250W x 24 VDC) to drive the predicate device. The subject device uses 2 pieces of LINIX, 120ZWN24-200, Brushless DC motor (200 W x 24 VDC) to drive the Joy Rider. The differences between the motors' specifications lead to the different performances of both devices, i.e., cruising range, max loading weight. There are no any new safety and effectiveness concerns raised for the subject device due to the different motors used.

Rear wheel size & type are different for the two devices, which are 10" x 2.25" (254 x 57 mm) and pneumatic tire for subject device with 30 psi and 12.5" x 2.25" (320 x 57 mm) for predicate device (PU solid tire). As seen from the data. the differences for the rear wheel size and type are small. These differences will not raise any new safety and effectiveness concerns for the subject device.

Maximum safe operational inclines for the devices are 10 degrees for the subject device and 8 degrees for the predicate device. According to the data, the subject device can move on the more inclined slope than the predicate device. There are no any new safety and effectiveness concerns raised by the different operational inclined slope for the subject device.

Unfolded dimensions for the subject device are 33.6" x 22.6" x 35.8" (855 x 580 x 910 mm) and are 37.4" x 22.6" x 36.2" (960 x 580 x 930 mm) for the predicate device, and the differences between two devices are so small and are validated by the compliance testing of RESNA WC-1 & WC-2 on the subject device. It is demonstrated there are no any new safety and effectiveness concerns raised by the unfolded dimensional differences for the subject device.

Folded dimensions (L x W x H) are 43.8" x 22.8" x 12.5" (1115 x 580 x 320 mm) for the subject device and 22.6" 12.6" 30.4" (580 * 325 *780 mm) for the predicate device. The differences are not small and the subject device has larger folded dimensions, and the smaller dimensions can bring about more convenient wheelchair

transfer than the subject device. The differences between two devices are validated by the compliance testing of RESNA WC-1 & WC-2 on the subject device. It is demonstrated there are no any new safety and effectiveness concerns raised by the unfolded dimensional differences for the subject device.

Travel range per full charge for the subject device is 9.3 miles (15 km) and 11.2 miles (18 km) for the predicate device. The difference of traveling range is due to the use of different batteries, different weights of user and other driving situations on the two devices. There are no any new safety and effectiveness concerns raised by this difference of travel range for the subject device.

Max Speed Backward is 2.4 mph (3.84 km/h) for subject device and 1.86 mph (3.0 km/h) for the predicate device. The difference of the max speed backward between two devices is small and there are no any new safety and effectiveness concerns raised by the difference of the max speed backward for the subject device.

Maximum obstacle climbing for two devices is 1.96” (50 mm) for subject device and 1.36” (34.5 mm) for predicate device. The data were measured per the ANSI RESNA WC-2:2019 Section 10 and are shown in the use manual to mitigate the risk due to the different obstacle climbing. Subject device has larger obstacle climbing and it is safer than the predicate device when climbing the obstacle. There are no any new safety and effectiveness concerns raised by the small difference of the maximum obstacle climbing for the subject device.

Electronic controller installed in the subject device is PG VR2 BLDC, Brushless double drive joystick controller and it is Changzhou Billon Electronic, WS-1 for the predicate device. The controlling software was installed on the electronic controller, which is referred to the MAF-2116 for Agency review. Since the control systems passed the requirements of ISO 7176-14 and RESNA WC-2:2008 section 14, their performances are surely validated. The differences of the electronic controller used by the predicate and subject devices will not raise any new safety and effectiveness concerns for the subject device.

- **CONCLUSIONS**

The subject device, Joy Rider, are as safe and effective as, and function in a manner equivalent to the predicate device, Nanjing Jin Bai He Medical Apparatus Co., Ltd., Powered Wheelchair, DYW30A(D09) K170787. The conclusions drawn from the non-clinical tests demonstrate that the subject device performs as well as the legally marketed device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.