April 18, 2024

Yongkang Yile Vehicle Co., Ltd.
℅ Evan Hu
Technical and Regulatory Director
Shanghai Mind-link Consulting Co., Ltd.
377 Tianzhu Road, Jiading
Shanghai, 201801
China

Re: K234098
Trade/Device Name: Mobility Scooter (C4+)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 22, 2023
Received: December 26, 2023

Dear Evan Hu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K234098

Device Name
Mobility Scooter (C4+)

Indications for Use *(Describe)*
The mobility scooter is intended for providing assistance to people restricted to a sitting 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.

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."

510(k) Summary

K234098

1. **Preparation date: Dec. 12th, 2023**

2. **Submitter**

Manufacturer: YONGKANG YILE VEHICLE CO., LTD.
Address: No.46 Zerong Road, Dahou Industrial Zone, Tangxian Town, Yongkang, Zhejiang, 321314, PRC
Contact person: David SHI, Chief Manager, +86 15158900066, 41724003@qq.com
Submission correspondent: Evan Hu, Technical and Regulatory Director, +86-18616124827, evan.ww.hu@outlook.com

3. **Device**

Trading name: Mobility Scooter (C4+)
Common name: Scooter
Regulation No.: 21 CFR 890.3800
Classification name: Vehicle, Motorized 3-Wheeled
Classification: Class II
Product code: INI

4. **Predicate device**

Predicate device: K132855
Trading name: HEARTWAY Power Mobility Scooter, S15
Common name: Scooter
Regulation No.: 21 CFR 890.3800
Classification name: Vehicle, Motorized 3-Wheeled
Classification: Class II
Product code: INI

5. **Device description**

The mobility scooter mainly consists of steal frame, two front wheels, two rear wheels, a seat, a tiller console, an electric motor, an electromagnetic brake, front lights, two rechargeable Lead-acid Batteries, and a battery charger. The product is intended to be used for assisting people restricted to a sitting position. It is driven by the end users for movement. It is compact, maneuverable but not necessarily able to overcome

obstacles. The maximum load is 150 kg. It is powered by rechargeable batteries with 25.3 km theoretical distance range which maximum speed up to 10.5 km/h (tested value).

The scooter is highly recommended to be driven on flat roads. Frequent usage of the scooter on slopes, rough terrain, or when climbing curbs will result in a reduction of driving distance.

6. Indications for use/Intended use

The mobility scooter is intended for providing assistance to people restricted to a sitting position.

7. Comparison of technological characters between proposed and predicate devices

Table 1. Characters comparison

Items	Proposed device (K-234098-Mobility Scooter, C4+)	Predicate device (K132855-HEARTWAY Power Mobility Scooter, S15)	Comments
Indications for use/Intended use	The mobility scooter is intended for providing assistance to people restricted to a sitting position.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	#1
Product code	INI	INI	Same
Frame and material	Folded, Cold rolled steel and seamless steel pipe	Folded, Carbon Steel Pipe	#2
Overall dimension	Length * width * height: 1366mm * 665mm * 1323mm	Length * width * height: 1400mm * 700mm * 1360mm	#2
Seat width Seat height	460mm 660mm	620mm 820mm	#2
Max occupant mass/Weight limit	150kg	160kg	#2
Overall weight	w/ batteries 130Kg (w/o package) w/o batteries 105Kg (w/o package)	w/ batteries 136Kg w/o batteries 98Kg	#2
Max speed	10.5km/h (tested value) 12km/h (set value)	9.6km/h	#2
Batteries	Lead acid battery Four batteries in two packs, 12V	Lead acid battery Two batteries packs, 12V DC, 50Ah.	#2

	DC, 20Ah.		
Range per charge/ Energy consumption	25.3km	40km	#2
Motor	24V DC, 950W	24V DC, 700 W	#2
Controller	PG S-DRIVE	RHINO DS120 Drive	#6
Brake	Electromagnetic brake	Electromagnetic brake	Same
Barking time and distance	<1s, 2.8m (min value at max forward speed on flat floor)	Not mentioned.	#2
Charger output	24V DC, 6A (IEC 60335-2-29 and ISO 7176-25 certified)	24V DC 4F24050 (UL E241359 certified)	Same
Rear wheel	320mm * 100mm, pneumatic* 2	13” * 3.5” (330mm*89mm) solid * 2	#2
Front wheel	320mm * 100mm, pneumatic* 2	13” * 5.0” (330mm*127mm) solid * 2	#2
Suspension	Macpherson suspension	Cross brace	#2
Incline	9 degrees	10 degrees	#2
Turning radius	1800mm	1280mm	#2
Ground clearance	1000mm	750mm	#2
Kerb climbing ability	100mm	80mm	#2
Armrest type	Flip backward	Flip backward	Same
Wheel lock	Push to lock	Push to lock	Same
Warranty	1 year: Main frame, controller, motor, battery.	3 years: Main frame 1 year: Controller / gear motor / batteries w/o exhaustive and wear parts	#3
User contacting components and materials	Foot pedal: PVC sheet Handlebar: PVC Seat, Seat belt: PVC fabrics Backrest, Armrest: PVC fabrics	Foot pedal: ABS Handlebar: PVC materials Seat, Seat belt: PVC materials Backrest, Armrest: PVC materials	#4
Biocompatibility	Complied with ISO 10993 serials	Complied with ISO 10993 serials	Same
Performance	Meet requirements of ISO 7176 serials	Meet requirements of ISO 7176 serials	Same
EMC	Meet requirements of ISO 7176-21:2009, IEC 60601-1-2: 2014+A1:2020, IEC TR 60601-4-2:2016.	Meet requirements of ISO 7176-21:2009, IEC 60601-1-2, ANSI / RESNA WC/Vol.2: 2009, CISPR 11: 2004+A2:2006, EN 61000-4-2: 2008, IEC 61000-4-3:2006, IEC 61000-4-8: 2001.	#5

Comments:

#1: The proposed and predicate devices have different wording in their Indications for Use,

but the meanings are the same and this does not affect the device's safety and effectiveness, demonstrating the substantial equivalence.

#2: The proposed device has different specifications for scooter components and performance compared to the predicate device. It underwent performance testing according to ISO 7176 series, and the results demonstrated that it met all the standard requirements. Therefore, both the proposed and predicate devices meet the performance testing standards, demonstrating the substantial equivalence.

#3: The main frame of the proposed device has a shorter warranty period compared to the predicate device. However, the warranty period for other components remains unchanged. This discrepancy in warranty period does not raise any safety or effectiveness concerns, demonstrating the substantial equivalence.

#4: The user-contact components only differ in the material used for the foot pedal, while the direct contact components remain unchanged. Biocompatibility testing has confirmed the long-term safety of use, demonstrating the substantial equivalence.

#5: The proposed and predicate devices for EMC testing both used the ISO 7176-21 standard. In addition, the proposed device underwent supplementary testing in accordance with the IEC 60601-1-2 and IEC 60601-4-2 standards, and both of these two standards encompass the testing methods outlined in the IEC 61000 series. The ANSI / RESNA WC/Vol.2 is the consensus standard of IEC 60601-1-2, Consequently, the use of different standards does not affect the EMC testing process, demonstrating the substantial equivalence.

#6: The proposed and predicate devices utilized distinct controllers with differing firmware configurations. Specifically, the proposed device employed the PG S-Drive controller, as cleared in K150987 and K191256. Performance testing of the controller was carried out in accordance with ISO 7176-14, yielding results that confirm adherence to the relevant standards. As a result, the utilization of different controllers has no bearing on the safety and effectiveness of the device, thereby demonstrating the substantial equivalence.

8. Non-clinical testing

PERFORMANCE TESTING

(1) EMC report was conducted according to ISO 7176-21:2009, IEC 60601-1-2: 2014+A1:2020, and IEC TR 60601-4-2:2016.
(2) Physical properties were conducted according to the following standards serials.
- ISO 7176-1:2014, Static stability
- ISO 7176-2:2017, Dynamic stability
- ISO 7176-3: 2012, Effectiveness of brakes
- ISO 7176-4:2008, Energy consumption and theoretical distance range
- ISO 7176-5:2008, Dimensions, mass and turning space

- ISO 7176-6:2018, Maximum speed, acceleration and deceleration
- ISO 7176-7:1998, Seating and wheel dimensions
- ISO 7176-8:2014, Static, Impact and fatigue strengths
- ISO 7176-9:2009, Climatic tests
- ISO 7176-10:2008, Obstacle-climbing ability
- ISO 7176-11:2012, Test dummies
- ISO 7176-13:1989, Coefficient of friction
- ISO 7176-14:2022, Power and control systems
- ISO 7176-15:1996, Information disclosure, documentation and labelling
- ISO 16840-10:2021, Resistance to ignition
- ISO 7176-22: 2014, Set up procedure
- ISO 7176-25: 2013, Battery and charger

BIOCOMPATIBILITY TESTING:
The proposed device was tested in compliance with the FDA Guidance document Use of International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”, as the Surface device- Intact skin-Long term contact (>30 days).
The items listed below underwent testing in accordance with ISO 10993-1.
- Cytotoxicity
- Intracutaneous Reactivity
- Sensitization

PACKAGE VALIDATION

Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging was deemed acceptable for protection of product.

USABILITY AND HUMAN FACTOR

A usability and human factor testing was conducted to assess the usability of the scooter from the users' perspective by following the FDA guidance-Applying Human Factors and Usability Engineering to Medical Devices. The results of observation and questionnaire indicated that users were generally satisfied with the scooter's usage and new risks were identified to be monitored.

9. Clinical testing

Not applicable for this submission**.**

10. Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.