



May 2, 2024

Zhejiang Innuovo Rehabilitation Devices Co., Ltd.
% Jarvis Wu
Senior Consultant
Shanghai Sungo Management Consulting Co., Ltd.
14th Floor, Dongfang Building
1500# Century Ave
Shanghai, Shanghai 200122
China

Re: K240012

Trade/Device Name: Mobility Scooter (W3431)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 17, 2024
Received: April 17, 2024

Dear Jarvis Wu:

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,

Julia E. Slocomb 2024.05.02

-S 18:48:09 -04'00'

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

Indications for Use

510(k) Number (if known)

K240012

Device Name

Mobility Scooter (W3431)

Indications for Use (Describe)

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.

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 K240012

Document Prepared Date: 2024/04/12

A. Applicant:

Zhejiang Innuovo Rehabilitation Devices Co.,Ltd

Address: No.196 Industry Road, Hengdian Movie Zone, Dongyang, Zhejiang,China

Contact Person: Grace Li

Tel: +86 15924234767

Submission Correspondent:

Primary contact: Mr. Jarvis Wu

Title: Senior Consultant

Shanghai SUNGO Management Consulting Co., Ltd.

14th Floor, Dongfang Building, 1500# Century Ave., Shanghai 200122, China

Tel: +86-21-58817802

Email: jiawei.wu@sungoglobal.com

Secondary contact: Mr. Raymond Luo

Title: Technical Director

Shanghai SUNGO Management Consulting Co., Ltd.

14th Floor, Dongfang Building, 1500# Century Ave., Shanghai 200122, China

Tel: +86-21-68828050

Email: zx FDA@sungoglobal.com

B. Device:

Trade Name: Mobility Scooter

Common Name: Scooter

Model: W3431

Regulatory Information

Classification Name: Motorized three-wheeled vehicle

Classification: Class II.

Product code: INI

Regulation Number: 890.3800

Review Panel: Physical Medicine

C. Predicate device:

510K number: K231428

Classification Name: Motorized three-wheeled vehicle

Regulation Number: 890.3800

Device Name: Mobility Scooter

Model: W3431D

D. Indications for use of the 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.

E. Device Description:

The Mobility Scooter, Model: W3431, has a base with Steel frame, two front wheel, two rear wheels, a seat, a tiller console, electric motor, electromagnetic brake, 2 rechargeable Lead-acid Batteries with an off-board charger. The movement of the scooter is controlled by the rider who operates the throttle lever, speed control dial and handle on the tiller console. The device is installed with an electromagnetic brake that will engage automatically when the scooter is not in use and the brake cannot be used manually. The Scooter only can be operated on the flat road.

F. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017, Wheelchairs - Part 2: Determination of dynamic stability of Powered Wheelchairs
- ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5, Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- ISO 7176-6: 2018, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of Powered Wheelchairs
- ISO 7176-7, 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 strengths
- ISO 7176-9:2009, Wheelchairs - Part 9: Climatic tests for Powered 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, First edition 1989-08-01, 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 16840-10:2021 Wheelchair seating Part 10: Resistance to ignition of postural support devices Requirements and test method.
- ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K231428)	Remark
Manufacturer	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd	Same
Common or Usual name	Scooter	Scooter	Same
Model(s)	W3431	W3431D	--
Indications for use	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.	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.	S.E.
Overall dimension	1020 mm x 500 mm x 840 mm	1020 mm x 500 mm x 840 mm	S.E.
Frame Material	Steel	Steel	S.E.
Frame style	Foldable seat, removable battery pack, disassemble for transport	Foldable seat, removable battery pack, disassemble for transport	S.E.
Front wheel size	190 x 55 mm	190 x 55 mm	S.E.
Front Wheels Quantity	2	2	S.E.
Rear wheel size	190 x 55 mm	190 x 55 mm	S.E.
Rear Wheels Quantity	2	2	S.E.
Ground clearance	45 mm	45 mm	S.E.
Max Loading(on level ground)	120kg	120kg	S.E.
Turn Radius	1650mm	1650mm	S.E.
Motor output	LINIX 24 V 180W	24 V 180W	Analysis
Drive System	Rear Wheel Drive	Rear Wheel Drive	S.E.

Zhejiang Innuovo Rehabilitation Devices Co.,Ltd
No.196 Industry Road, Hengdian Movie Zone, Dongyang, Zhejiang, China

Brakes	Electromagnetic brake	Electromagnetic brake	S.E.
Battery	Long Way Lead-acid 12V12Ah*2	Lead-acid 12V12Ah*2	Analysis
Charger	24V/2A	24V/2A	S.E.
Max Speed	6 km/h	6 km/h	S.E.
Slope Grade Ability	9 degree	9 degree	S.E.
Travel Distance	15 km/9.32 Miles	15 km/9.32 Miles	S.E.
Arm Rests (Distance between armrests)	44-56 cm	44-56 cm	S.E.
Controller	PG45A	PG45A	S.E.
Time to brake	0.7-1s	0.7-1s	S.E.
Brake Distance- Normal operation (Horizontal- Forward- Max speed)	≤1.5m	≤1.5m	S.E.
Battery weight	8.8kg	8.8kg	S.E.
Base weight (not including battery)	42kg	42kg	S.E.
Operating surface & environment	Indoor use and restricted outdoor use on pavements or paved footpaths only.	Indoor use and restricted outdoor use on pavements or paved footpaths only.	S.E.
Remote control	None	None	S.E.

I. Difference analysis

The design and technological characteristics of the proposed device scooter is identical to the predicate device. There are minor differences between the device is the brand/suppliler of battery and motor. and the proposed device uses Long Way Lead-acid Batteries and LINIX 180W Motor.

According to ISO7176 series standards and the test records support its safety and effectiveness. There is no deleterious effect on safety and effectiveness due to the minor differences do not influence the intended use of the device. Therefore, the proposed Scooter is substantially equivalent (SE) to The Scooter (K231428).

The Mobility Scooter Model W3431 in its final finished form is identical to the Mobility Scooter Model W3431D in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents)

Table 2 Safety comparison

Item	Proposed Device	Predicate Devices	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	S.E.
EMC	ISO7176-21 and IEC 60601-1-2	ISO7176-21	S.E.
Performance	ISO7176 series	ISO7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Table 3 Safety comparison

Item	Proposed Device	Predicate Devices	Results
ISO7176-1	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet its design specification.	S.E.
ISO7176-2	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification.	The dynamic stability has been determined after the testing according to the ISO 7176-2, and test results meet its design specification.	S.E.
ISO7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	S.E.
ISO7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	S.E.
ISO7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	S.E.
ISO7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	S.E.
ISO7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	S.E.
ISO7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	S.E.
ISO7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8	S.E.

	of ISO 7176-9	of ISO 7176-9	
ISO7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	S.E.
ISO7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	S.E.
ISO7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	S.E.
ISO7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	S.E.
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	S.E.
ISO7176-16/ ISO 16840-10:2021	The performance of resistance to ignition meet the requirements of ISO 16840-10:2021	The performance of resistance to ignition meet the requirements of ISO 7176-16	S.E.
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	S.E.
ISO7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	S.E.

J. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Mobility scooter, model W3431, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K231428.