October 9, 2024

Zhejiang Innuovo Rehabilitation Devices Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai, 200122
China

Re: K242387
Trade/Device Name: Mobility Scooter (N3473)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: August 12, 2024
Received: August 12, 2024

Dear Ivy Wang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242387

Device Name

Mobility Scooter

Indications for Use *(Describe)*

The mobility scooter 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.

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

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510(k) Summary

K242387

I. Applicant

Name: Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

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

Name of contact person: Grace Li

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Date prepared: 2024-10-04

II. Submission Correspondent

Ms. Ivy Wang

Shanghai Sungo Management Consulting Co., Ltd.

Tel: +86-21-5881 7802

Email: haiyu.wang@sungoglobal.com

III. Device

Device trade name: Mobility Scooter

Model: N3473

Regulatory Information:

Classification name: Vehicle, motorized 3-wheeled

Regulation class: 2

Regulation number: 21CFR 890.3800

Panel: Physical Medicine

Product code: INI

IV. Predicate device

K201196

Device Name: Scooter

Model: FDB01

Nanjing Jin Bai He Medical Apparatus Co. Ltd.

V. Device description

This mobility scooter 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 Mobility Scooter, Model N3473, has a base with magnesium alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, a tiller console, an electric motor, an electromagnetic brake, 1 rechargeable Lithium Battery with an off-board charger, a remote control switch. 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.

VI. Indication for use

The mobility scooter 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.

VII. Comparison with the predicate device

Table 1 General Comparison

Attribute	Subject device	Predicate device	Results
Manufacturer	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	Nanjing Jin Bai He Medical Apparatus Co. Ltd.	/
Proprietary name, model	Mobility Scooter N3473	Scooter, FDB01	/
510(k) number	K242387	K201196	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3800	21 CFR 890.3800	Same
Product code	INI	INI	Same
Similarities			
Indication for use	The mobility scooter is a motor driven, indoor and outdoor transportation vehicle with the intended	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a	Same

Attribute	Subject device	Predicate device	Results
	use to provide mobility to a disabled or elderly person limited to a seated position.	disabled or elderly person limited to a seated position.	
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake	Electromagnetic	Electromagnetic	Same
Time to brake	< 1 s	< 1 s	Same
Controller	PG45A	PG45A	Same
Frame style	Foldable seat, removable battery pack, disassemble for transport	Foldable seat, removable battery pack, disassemble for transport	Same
Folding mechanism	Seat can be folded; battery can be dismantled；The frame can be folded back and forth.	Seat can be folded; battery can be dismantled；The frame can be folded back and forth.	Same
Setting Design	One-click folding intelligent electric scooter, with a sensitive remote control, gently press, the scooter automatically completed folding contraction, folding volume small, electromagnetic automatic brake, the overall simple design, convenient and practical, Travel does not have to consume physical force to do folding, poor physical strength and the elderly the best walking tool.	One-click folding intelligent electric scooter, with a sensitive remote control, gently press, the scooter automatically completed folding contraction, folding volume small, electromagnetic automatic brake, the overall simple design, convenient and practical, Travel does not have to consume physical force to do folding, poor physical strength and the elderly the best walking tool.	Same
Battery	Lithium battery 24V/12AH	Lithium battery 24V/6AH*2	Same
Max loading weight	120 kg	120 kg	Same
Brake distance	1.1m	1.1m	Same

Attribute	Subject device	Predicate device	Results
Dynamic Stability	6 °	6°	Same
Max speed	6 km/h	6 km/h	Same
Differences			
Main frame material	Magnesium alloy	Aluminum alloy	Different
Maximum distance of travel on the fully charged battery	17 km	20km	Different
Overall Dimension (length*width*height)	970*580* 950mm	1050mm*550mm * 870mm	Different
Turning Radius	1350 mm	1200 mm	Different
Ground clearance	65 mm	50mm	Different
Maximum obstacle climbing	15 mm	60 mm	Different
Front wheel size/type	7” PU solid tire	7” Solid tire	Same
Rear wheel size/type	8” PU solid tire	8” Solid tire	Same
Motor	24 V 150W	24 V 180W	Different
Charger	Input: 100-240Vac, 50-60Hz, 1.1A Output: 24V/2A	Input: 100-240Vac, 50-60Hz, 1.2-0.5A Output: 24V/2A	Different

Difference Analysis:

The design and technological characteristics of the subject device is basically similar to the predicate device chosen. There are minor differences between the devices including frame material, travel distance, overall dimensions, turning radius, obstacle climbing ability, Ground clearance, charger and motor specification. There is no deleterious effect on safety and effectiveness due to the differences, and these minor differences do not influence 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.

Therefore, the subject device is substantially equivalent to the Scooter (K201196).

Table 2 Safety comparison

Attribute	Subject device	Predicate device	Results
Biocompatibility	All user directly contacting materials are compliance with	All user directly contacting materials are compliance	S.E.

Attribute	Subject device	Predicate device	Results
	ISO10993-5, ISO10993-10, requirements.	with ISO10993-5 and ISO10993-10 requirements.	
EMC	ISO7176-21 & 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

Attribute	Subject device	Predicate device	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 maximum speed, acceleration and deceleration of scooter has been determined after the testing according to the ISO 7176-6	The maximum speed, acceleration and deceleration of scooter has been determined after the testing according to the ISO 7176-6	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	All test results meet the requirements in Clause 4 of ISO	S.E.

Attribute	Subject device	Predicate device	Results
	7176-8	7176-8	
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 of ISO 7176-9	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 of ISO 7176-9	S.E.
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.
ISO 7176-16/ ISO 16840-10	The performance of resistance to ignition meets the requirements of ISO 16840-10.	The performance of resistance to ignition meets the requirements of ISO 7176-16.	S.E.
ISO7176-21/ IEC 60601-1-2	The EMC performance results meet the requirements of ISO 7176-21 & IEC 60601-1-2	The EMC performance results meet the requirements of ISO 7176-21	S.E.
ISO7176-22	All performed tests are set up as requirements of ISO 7176-22	All performed tests are set up as requirements of ISO 7176-22	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.

VIII. 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 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
- ISO 7176-3:2012 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 7176-6:2018 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 7176-14:2022 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

- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25:2013 Wheelchairs - Batteries and chargers for powered wheelchairs
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020.

IX. Summary of clinical testing

No clinical study is included in this submission.

X. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K201196.