November 20, 2024

Zhejiang Nysin Medical Co., Ltd.
% Boyle Wang
Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K241603
Trade/Device Name: Powered Wheelchair (NXN20-208, NXN20-211)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: October 21, 2024
Received: October 21, 2024

Dear Boyle 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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241603

Device Name

Powered Wheelchair (NXN20-208, NXN20-211)

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.

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

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510(k) Summary

K241603

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

1.0 Submitter's information

Name: Zhejiang Nysin Medical Co., Ltd.
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Contact: Zhang Xiaoying

Designated Submission Correspondent

Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: Mar.28, 2024

2.0 Device information

Trade name: Powered Wheelchair
Common name: Powered Wheelchair
Classification name: Powered Wheelchair
Model(s): NXN20-208, NXN20-211

3.0 Classification

Production code: ITI
Regulation number: 21 CFR 890.3860
Classification: Class II
Panel: Physical Medicine

4.0 Predicate device information

Manufacturer: Kunshan Aoshida Electric Technology Co., Ltd.
Trade/Device: A08 Power Wheelchair

510(k) number: K163204

5.0 Indication for Use Statement

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.

6.0 Device description

The subject device, Powered Wheelchair, mainly powered by battery, motivated by DC motor, driven by user controlling joystick and adjusting speed.
The Powered Wheelchairs consist of two foldable armrests, a backrest, a seat cushion, a safety belt, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, two Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.
The NXN20-208 and NXN20-211 Powered Wheelchair is intended to provide mobility to a disabled or elderly person limited to a seated position.
The Powered Wheelchair has 7 inch front wheel and 11 inch rear tire.
The motor of electric wheelchair is DC24V 200W; the battery is 24V 12AH, Li-ion battery; the charger is 24V/3A.
Max. loading can not be over than 110Kgs.
Max. distance of travel on the fully charged battery is 16 km and Max. speed forward is 6km/h.
The braking time is about 2s, and the braking distance is ≤1.77m.

7.0 Summary of Non-Clinical Testing

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 electrically powered 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 overall dimensions, mass and manoeuvring 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 strengths
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 7176-14:2008 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 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
ISO 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Content of Premarket Submissions for Device Software Functions for software.
The Software Validation is in compliance with FDA Guidance.

8.0 Summary of Clinical Testing

No clinical study implemented for the electric wheelchair.

9.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Proposed device		Predicate device	Remark
Product Code	ITI		ITI	Same
Regulation No.	21 CFR 890.3860		21 CFR 890.3860	Same
Class	II		II	Same
Product name	Powered Wheelchair		A08 Power Wheelchair	-
510(k) No.	K241603		K163204	-
Models	NXN20-208	NXN20-211	A08	-
Intended Use	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.		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.	Same
Use environment	Indoor and outdoor use		Indoor and outdoor use	Same
Patient Population	This product is suitable for disabled people with mobility difficulties and elderly people.		This product is suitable for disabled people with mobility difficulties and elderly people.	Same
Product structure	Consist of two foldable armrests, a backrest, a seat cushion, a safety belt, a foldable frame, two rear driving wheels with hub motor/electromagnetic brake assemblies, two pivoting casters, two Li-ion batteries, an off-board battery charger, a control panel, and an electric motor controller.		Consists primarily of a foldable welded-aluminum frames, two sealed transaxle motors drive system, electromagnetic braking system, electric motor controller and two Li-ion batteries with an off-board battery charger.	Similar
Driving system	Direct drive on the rear wheels		Direct drive on the rear wheels	Same
Movement control method	By Joystick control		By Joystick control	Same
Number of wheels	4		4	Same
Brake system	Automatic electromagnetic brake system		Electromagnetic brake system	Same
Main frame material	Model NXN20-208 consists of Aluminum alloy, and model NXN20-211 consist with Aluminum alloy+Carbon fiber.		Welded-aluminum	Different The differences in the main frame material will not impact the safety and effectiveness of the substantial equivalence.

Motor	Brushless motor, DC24V* 200W*2pcs	Brushless motor, 24 VDC *250W * 2 pcs	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Battery	DC 24V 12Ah Lithium-ion, 2 pcs	Lithium-ion 20 Ah x 24 VDC	
Battery charger	Off-board charger Input: 100-240 VAC Output: DC 24V, 3A	Off-board charger Input: 110-240 VAC Output: DC 24V, 2 Amp	

Table2 Performance Comparison

Item	**Subject Device**		**Predicate Device**	**Remark**
Model	NXN20-208	NXN20-211	A08	--
Overall length	1000mm	950mm	890 mm	Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.
Overall width	600mm	600mm	603 mm	
Stowage length	340mm	340mm	324 mm	
Stowage width	600mm	600mm	603 mm	
Stowage height	775mm	765mm	670 mm	
Weight, w/ Battery	42.99 lbs. /19.5kg	36.48 lbs. /16.55kg	61.7 lbs. /28 kg	The difference will not raise any new safety and effectiveness concerns.
Front wheel (inch)	7 (PU solid tire)		8 (PU solid tire)	Smaller sizes of font wheels
Rear tire (inch)	11 (PU solid tire)		10 (PU solid tire)	Larger sizes of rear wheels bring steadier pivoting function than predicate device.
Cruising Range (km)	16		20	The subject device complies with ISO 7176-4: 2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance

			range, these differences do not affect safety and effectiveness.
Obstacle climbing(mm)	25	40	The smaller height in the obstacle climbing will not impact the safety and effectiveness of the subject device.
Static stability forward	18.8°	Not publicly available	Both of the devices are evaluated according to standard ISO 7176-1:2014, so the different static stability will not impact the safety and effectiveness
Static stability rearward	20.4°		
Static stability sideways	20.5°		
Max. loading (kg)	242.5lbs(110kg)	220 lbs (100 kg)	More loading weight means more convenient for the transportation
Min. Turning radium	850mm / 840mm	800mm	Similar
Minimum braking distance	⩽1.77m	1m	Similar
Max Speed Forwards	1.66 m/s (6 km/h)	1.94 m/s (7 km/h)	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Max. Speed Backward	0.8 m/s (2.88 km/h)	Not publicly available	The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness
Controller	Yanteon Mechanical & Electronic Technology	Yisheng Electric Co. Ltd ,	Different Although different

	(Shanghai) Co. Ltd. Joystick Y2450M Controller Y2430M	WS-1, 40A	controller is used, both the control system, including the joystick controller, the electromagnetic brakes and the user interface are similar. The joystick controls the directions and speed of movement, and when the joystick is released, the powered wheelchair will slow down to stop and the brakes will automatically re-engage. The controller also provides the battery status displaying and abnormal condition displaying. Both of the control systems are evaluated according to standard ISO 7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference.
Speed control method	Joystick control method	Joystick control method	Same

Table3 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Materials contacting user	Armrest: PU; Backrest/Seat/Seat belt: Sandwich mesh fabric (polyester) Safety Belt: Nylon	Armrest: PU; Backrest/seat cushion: PU foam covered by nylon fabric cloth	Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concerns due

	Controller Housing: ABS Joystick/button: Silicone Footplates: ABS		to the difference.
Biocompatibility of materials contacting user	Comply with FDA Guidance	Comply with ISO 10993-1, FDA Guidance, Tests included Cytotoxicity (ISO 10993-5:2009), Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010)	Same

Summary of substantial equivalence discussion:

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device under K163204.