January 29, 2026

Zhejiang Nysin Medical Co., Ltd.
% Lord Guo
Regulatory Director
Orscene (Shanghai) Medical Technology Co., Ltd.
Room 118, Building 20, No. 1-42, Lane 83, Hongxiang North Rd
Lingang New Zone, China (Shanghai) Pilot Free Trade Zone
Shanghai, China

Re: K252275
Trade/Device Name: Electric Scooter (DDF100)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: January 2, 2026
Received: January 2, 2026

Dear Lord Guo:

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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252275

Please provide the device trade name(s).

Electric Scooter (DDF100)

Please provide your Indications for Use below.

The electric 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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252275

510(k) Summary

Prepared on: 2026-01-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zhejiang Nysin Medical Co., Ltd.
Applicant Address	No. 305 Jiulong North Road, Dongcheng District, Yongkang Jinhua Zhejiang 321000 China
Applicant Contact Telephone	0579-87153722
Applicant Contact	Mrs. Xiaoying Zhang
Applicant Contact Email	wm01@chinaqianxi.com
Correspondent Name	Orscene (shanghai) Medical Technology Co., Ltd.
Correspondent Address	Room 118, Building 20, No. 1-42, Lane 83, Hongxiang North Road Lingang New Zone, China (Shanghai) Pilot Free Trade Zone shanghai shanghai China
Correspondent Contact Telephone	+86 18521500818
Correspondent Contact	Mr. Lord Guo
Correspondent Contact Email	lord.guo@orscene.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Electric Scooter (DDF100)
Common Name	Motorized three-wheeled vehicle
Classification Name	Vehicle, Motorized 3-Wheeled
Regulation Number	890.3800
Product Code(s)	INI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201196	Scooter (Model: FDB01)	INI
K242982	Mobility Scooter (MS160A)	INI

Device Description Summary

21 CFR 807.92(a)(4)

The electric 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 DDF100, consists with two front wheels, two rear wheels, two rear anti-tip wheels, one seat system with one back support and two arm supports, an adjustable steering column, a tiller console, an electric motor, an electromagnetic brake, one rechargeable Lithium-Ion battery and one off-board charger.

The movement of the wheelchair is controlled by the speed lever and steering column. The device is installed with an electromagnetic brake that will engage automatically when the wheelchair is not in use and the brake can be manually adjusted to free wheel mode. The scooter only can be operated on the flat road.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The electric 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the subject device and predicate devices are motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Technological Comparison

21 CFR 807.92(a)(6)

The design and technological characteristics of the Electric Scooter is similar to the predicate device. All of the parameters with differences cannot raise safety and effectiveness concerns based on performance tests according to ISO7176 series standards. In conclusion, the subject device is substantially equivalent (SE) to the Scooter (K201196&K42982). The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

EN 12184:2022 Electrically powered wheelchairs, scooters and their chargers- Requirements and test methods
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 of electrically powered 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 7176-14:2022 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 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
ISO 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices – Requirements and test method

N/A, no clinical study conducted.

Performance testing demonstrated that the subject device is as safe and effective as the predicate.