October 6, 2025

Nanjing Kangni Smart Technology Co.,Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K252502
Trade/Device Name: Folding Mobility Scooter (KD101)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: August 8, 2025
Received: August 8, 2025

Dear Eva Li:

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

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.	K252502

Please provide the device trade name(s).

Folding mobility scooter (KD101)

Please provide your Indications for Use below.

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.

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) Summary

Date prepared: Aug 8,2025

1. Submitter

Application Information:
Submitter: Nanjing Kangni Smart Technology Co.,Ltd.
Address: No.4 Gupinggang, Gulou District, Nanjing, China
Manufacturing address： No.11 Hengjing Rd, Economic & Technological Development Zone, Nanjing, China
Contact name: Yu Huilin
Title: Registered Engineer
Email: yuhl2@kn-nanjing.com

2. Device

Device Name： Folding mobility scooter
Model: KD101
Classification: II
Product Code: INI
Regulation:890.3800
Panel: Motorized three-wheeled vehicle

3. Predicate Device

510Knumber: K231428
Device Name: Mobility Scooter
Model: W3431D
Zhejiang Innuovo Rehabilitation Devices Co.,Ltd.

4. Device Description

The Folding mobility scooter, has a base with metal frame, two front wheels, two rear wheels, a seat, a LED Display, electric motor, electromagnetic brake, 1 rechargeable Lithium Battery pack (with 2 batteries) with an off-board charger. The movement of the scooter is controlled by the rider who operates the control lever. 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. The device can be folded up from front to back.

The device has 2 options, with a faucet adjustment or without a faucet adjustment.

5. Indication 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.

6. Comparison of technological characteristics with the predicate device

Elements of Comparison	Subject Device	Predicate Device (K231428)	Remark
Manufacturer	Nanjing Kangni Smart Technology Co.,Ltd.	Zhejiang Innuovo Rehabilitation Devices Co.,Ltd	Same
Device name	Folding mobility scooter	Mobility Scooter	Same
Model(s)	KD101	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.	Same
Overall dimension	With a faucet adjustment: 990mm x 576mm x730mm Without a faucet adjustment: 970 mm*576mm*705mm	1020 mm x 500 mm x 840 mm	Similar
Frame Material	Steel	Steel	Same
Frame style	Foldable tiller, Foldable seat, removable battery pack, disassemble for transport	Foldable seat, removable battery pack, disassemble for transport	Similar
Rear Wheels Quantity	2	2	Same
Ground clearance	25 mm	45 mm	Similar
Max occupant mass	125kg	120kg	Same
Min Turn Radius	1400mm	1650mm	Similar
Motor output	24 V 180W	24 V 180W	Same
Drive System	Rear Wheel Drive	Rear Wheel Drive	Same
Brakes	Electromagnetic brake	Electromagnetic brake	Same
Battery	Li-ion Battery 24V 6Ah*2	Lead-acid 12V12Ah*2	Similar
Charger	24V/2A	24V/2A	Same
Max Speed	7 km/h	6 km/h	Similar
Max Slope	8°	9°	Similar
Travel Distance	15.6 km	15 km	Similar

Time to brake	1 s	0.7-1s	Similar
Brake Distance-Normal operation (Horizontal-Forward- Max speed)	≤1.09m	≤1.5m	Similar
Total mass	With a faucet adjustment:26.6Kg Without a faucet adjustment:26.15Kg	42kg	Similar
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.	Same
Remote control	None	None	Same

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-1	All user directly contacting materials are compliance with ISO10993-1	Same
EMC	ISO7176-21& IEC 60601-1-2:2014+A1:2020	ISO7176-21& IEC 60601-1-2:2014+A1:2020	Same
Performance	ISO7176 series	ISO7176 series	Same
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	Same

Substantial Equivalence Discussion

The proposed device and predicate device are complying to the same ISO standards, ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-7, ISO 7176-8, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 7176-16, ISO 7176-21, ISO 7176-25, and FDA guidance Submission for Scooter.

The proposed device performs in a similar manner to the predicate device. All these tests have corresponding requirements/ control criteria following above mentioned standards. And the test results show that the subject product is substantially equivalent to the predicate device in performance.

The performance testing demonstrates that the subject device is substantially equivalent to the predicate devices regarding Static ability (Scooter tipping angle), The Dynamic stability (Safe Gradient Maximum Gradient), Brake performance, Theoretical distance range, Dimension and weight, Maximum speed, Dimension of wheel Static, impact and fatigue strengths, Climatic tests, Obstacle-climbing ability, Dummy, friction of test surfaces, Power and control systems, Documentation and labeling, Resistance to ignition, Electromagnetic Compatibility and Electrical Safety, Batteries and chargers.
The non-clinical laboratory data support the safety and performance of the subject

device and demonstrate that the subject device should perform as intended in the specified use conditions.

7. Summary of non-clinical testing

- Performance testing-bench

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination

- Software validation
- 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 7176-31:2023 Wheelchairs – Lithium-ion Battery systems and chargers for powered wheelchair-Requirements and test methods
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- **Biocompatibility of patient-contacting material**

The biocompatibility of the subject device was determined via the declaration of identical tissue-contacting materials to the predicate device, which evaluated biocompatibility according to the ISO 10993-1.

8. Summary of clinical testing

No animal study and clinical studies are available for our device. Clinical testing was not

required to demonstrate the substantial equivalence of the electric wheelchair to its predicate device.

9. 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 K231428.