



September 24, 2026

Anhui Jbh Medical Apparatus Co., Ltd.
% Amos Zou
Medical Device Consultant
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Rm. 703, Bldg. 16, S. Bank Plz., Exhibition Bay
Zhancheng Community, Fuhai St., Bao'An District
Shenzhen, Guangdong 518053
China

Re: K261078
Trade/Device Name: Electric Scooter (FNS01, FNS03)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 1, 2026
Received: April 1, 2026

Dear Amos Zou:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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.

K261078

?

Please provide the device trade name(s).

?

Electric Scooter (FNS01,FNS03)

Please provide your Indications for Use below.

?

The Electric Scooter is intended for medical purposes to provide mobility to persons restricted to a sitting position.

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

☐ Prescription Use ([21 CFR 801 Subpart D](#))

☒ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

-K261078

1. Submitter Information

Sponsor:

Item	Information
Submitter's Name	Anhui JBH Medical Apparatus Co., Ltd.
Address	# 116 Qicang Rd., Industrial District, Ming Guang City, Chuzhou, Anhui, CN
Contact Person	Yuanwei Wei
Phone Number	+86-0550-8108866
Email	outreach@jbhmedical.com

Application Correspondent:

Item	Information
Company Name	Huide Medical Technology Service Group Co., Ltd
Address	Room 703, Building 16, South Bank Plaza, Exhibition Bay, Zhancheng Community, Fuhai Street, Shenzhen, Guangdong, 518053, China
Contact Person	Mr. Amos Zou
TEL	+86-15015249549
E-mail	546977693@qq.com
Prepared Date	August 23, 2026

2. Device Identification

Item	Subject Device 1	Subject Device 2
Device Trade Name	Electric Scooter (Model: FNS01)	Electric Scooter (Model: FNS03)
Common Name	Motorized Vehicle / Electric Scooter	Motorized Vehicle / Electric Scooter
Classification Name	Vehicle, Motorized 3-Wheeled	Vehicle, Motorized 3-Wheeled
Regulation Number	21 CFR 890.3800	21 CFR 890.3800
Regulatory Class	Class II	Class II
Product Code	INI	INI
Panel	Physical Medicine	Physical Medicine

3. Predicate Device Information

Item	Predicate Device
510(k) Number	K252349
Device Name	Electric Scooter (Model: Mojo-T330)
Manufacturer	Dongguan Smarfody Mobility Technology Co., Ltd.

Product Code	INI
Regulation Number	21 CFR 890.3800
Regulatory Class	Class II

The predicate device has not been subject to a design-related recall.

4. Device Description

The subject devices (FNS01 and FNS03) are motor-driven, indoor and outdoor transportation vehicles designed to provide mobility to persons restricted to a sitting position.

FNS01 (4-Wheel Model): The device consists of an aluminium alloy frame, 4 wheels (Front: 6.3" PU solid, Rear: 7.5" PU solid), a seat, a control panel (tiller), a 120W electric motor, an electromagnetic brake system, dual rechargeable Lithium-ion batteries (24V 6AH x 2 pcs), an off-board charger, and a Bluetooth BLE 5.0 module with a dedicated Bluetooth key (remote controller). The device features a manual folding mechanism for portability.

FNS03 (3-Wheel Model): The device consists of an aluminium alloy frame, 3 wheels (Front: 8" PU solid, Rear: 7.5" PU solid), a seat, a control panel (tiller), a 150W electric motor, an electromagnetic brake system, a single rechargeable Lithium-ion battery (24V 6AH x 1 pc), and an off-board charger. The device has no Bluetooth function and relies solely on on-board manual/electric controls. The device features a manual folding mechanism for portability.

Control System: The movement is controlled by the rider via a control lever. The FNS01 model additionally incorporates a Bluetooth BLE 5.0 module with a dedicated Bluetooth key (remote controller). This remote control function enables the user to remotely power the scooter on/off, fold/unfold, and lock/unlock it, providing convenient remote operation for users with limited mobility who may have difficulty reaching or operating the control panel. The Bluetooth key has no network capability; the device has no internet connectivity and no over-the-air (OTA) update path. The electromagnetic brake engages automatically when the scooter is not in use or the control lever is released.

5. Indications for Use

The Electric Scooter is intended for medical purposes to provide mobility to persons restricted to a sitting position.

6. Technological Characteristics Comparison

The subject devices share the same fundamental technological characteristics and design principles as the predicate device (K252349). A detailed comparison is provided below:

Elements of Comparison	Subject Device (FNS01)	Subject Device (FNS03)	Predicate Device (K252349)	Comparison Result
Indications for Use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position	Same
Regulation Number	21 CFR 890.3800	21 CFR 890.3800	21 CFR 890.3800	Same
Product Code	INI	INI	INI	Same
Classification	Class II	Class II	Class II	Same
Number of Wheels	4 Wheels	3 Wheels	4 Wheels	Similar
Foldable Mechanism	Yes (Manual Folding)	Yes (Manual Folding)	Yes (Foldable)	Same
Maximum Loading	120 kg	120 kg	120 kg	Same
Maximum Speed	6 km/h	6 km/h	6 km/h	Same

Power Source	Rechargeable Li-ion Battery	Rechargeable Li-ion Battery	Rechargeable Li-ion Battery	Same
Brake System	Electromagnetic Brake	Electromagnetic Brake	Electromagnetic Brake	Same
Control Method	Tiller/Control Lever	Tiller/Control Lever	Tiller/Control Lever	Same
Wireless Communication / Remote Control	Bluetooth BLE 5.0 remote control (dedicated Bluetooth key)	None	None	Different (FNS01 only)
Frame Material	Aluminium Alloy	Aluminium Alloy	Metal frame	Similar
Motor Power	120W	150W	Electric motor	Similar
Battery Configuration	24V 6AH x 2 pcs	24V 6AH x 1 pc	1 rechargeable Li-ion Battery	Similar
Device Dimensions — Unfolded (L×W×H)	946 × 495 × 926 mm	1010 × 525 × (830–1030) mm	1120 × 580 × 700 mm	Similar
Device Dimensions — Folded (L×W×H)	418 × 495 × 693 mm	360 × 525 × 650 mm	730 × 450 × 420 mm	Similar
Ground Clearance	20 mm	65mm	Not specified in predicate labeling	—
Front Wheel Size & Type	6.3 in (163 × 50 mm) PU solid	8 in (200 mm) PU solid	~7 in (175 × 40 mm)	Similar
Rear Wheel Size & Type	7.5 in (190 × 54 mm) PU solid	7.5 in (190 × 54 mm) PU solid	~7 in	Similar
Max. Travel Distance (full charge)	15.6 km	15 km (1 batt.) / 30 km (2 batt.)	Not specified in predicate labeling	—
Minimum Braking Distance	≤1.0 m (level) / ≤1.6 m (3°)	≤1.0 m / ≤1.6 m [not in IFU]	Not specified in predicate labeling	—
Maximum Safe Operation Incline	8°	6°	Not specified in predicate labeling	—
Minimum Turning Radius	1200 mm	1000 mm	Not specified in predicate labeling	—
Maximum Obstacle Climbing	20 mm height / 100 mm gap	25 mm height / 100 mm gap	Not specified in predicate labeling	—

Remark:

Based on the comparison and analysis above:

1. The subject devices (FNS01 and FNS03) have the same intended use as the predicate device (K252349).
2. The subject devices share the same fundamental technological characteristics as the predicate (power source, braking system, control mechanism, and folding design) and the same regulatory classification.
3. The key safety and performance parameters — maximum load (120 kg) and maximum speed (6 km/h) — are identical to the predicate.
4. The differences in technological characteristics (number of wheels, device dimensions and folded size, ground clearance, front/rear wheel size and type, maximum travel distance, minimum braking distance, maximum safe operation incline, minimum turning radius, maximum obstacle climbing, motor power, and battery configuration) are minor design variations that do not affect safety or effectiveness. In addition, FNS01 integrates a Bluetooth BLE 5.0 remote-control function (via a dedicated Bluetooth key) that the predicate does not have; this function has been verified through dedicated remote-control testing and a complete cybersecurity assessment and does not introduce any new safety or effectiveness concern.

7. Non-Clinical and/or Clinical Tests Summary & Conclusions

To demonstrate substantial equivalence, the subject devices (FNS01 and FNS03) were tested in accordance with recognized consensus standards and FDA guidance. The testing included:

7.1 Performance Testing

The devices were tested according to the ISO 7176 series standards and EN 12184:2022. Test results demonstrated that the subject devices perform as intended and are substantially equivalent to the predicate device regarding:

- Static and Dynamic Stability (Scooter tipping angle, Safe Gradient)
- Brake Performance
- Maximum Speed (6 km/h) and Theoretical Distance Range
- Dimensions and Weight
- Obstacle-climbing Ability
- Static, Impact, and Fatigue Strengths
- Climatic Tests
- Power and Control Systems
- Flammability / Resistance to Ignition (ISO 16840-10:2021/Amd.1:2024)

7.2 Biocompatibility

The biocompatibility evaluation for the subject device was conducted in accordance with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". As dictated by the nature of body contact (intact skin) and contact duration (More than 30 days), the following endpoints were evaluated for the components that come into direct contact with the user (e.g., grips):

- 1) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- 2) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- 3) ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

The results of these test demonstrated that the patient-contacting components of the subject device are non-cytotoxic, non-sensitizing, and non-irritating.

7.3 Electrical Safety and EMC

The devices comply with applicable electrical safety and electromagnetic compatibility standards. EMC testing (IEC 60601-1-2 Edition 4.1 2020-09; IEC TS 60601-4-2 Edition 1.0 2024-03) demonstrates compliance with emission and immunity requirements, confirming the device does not interfere with other medical equipment and operates safely in its intended environment.

7.4 Software Verification and Validation Testing

In compliance with the requirements specified in the U.S. Food and Drug Administration (FDA) guidance document for industry and FDA staff—Content of Premarket Submissions for Device Software Functions—Software System testing results provided in this 510(k) demonstrate that all software requirement specifications have been met, and all software-related hazards have been mitigated to acceptable risk levels. The software verification and validation documentation includes dedicated remote-control (Bluetooth key) testing for the FNS01 model, covering power on/off, fold/unfold, pairing, AES encryption, fault injection, and misoperation prevention.

7.5 Cybersecurity

The FNS01 model incorporates a Bluetooth BLE 5.0 interface (dedicated Bluetooth key remote controller). In accordance with Section 524B of the FD&C Act and the FDA guidance "Cybersecurity in Medical Devices", a complete cybersecurity documentation set was provided, including a threat model (STRIDE), a cybersecurity risk assessment (CVSS 4.0 + NIST SP 800-30 R3), a Software Bill of Materials (SBOM), architecture views, cybersecurity controls, cybersecurity testing, cybersecurity labeling, and a cybersecurity management plan. Third-party penetration testing identified 11 low-severity findings, all assessed as acceptable. The device is a standalone, offline device with no internet connectivity; its attack surface is limited to the Bluetooth pairing interface and the physical offline firmware update interface.

7.6 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Substantial Equivalence Conclusion

The subject devices (Electric Scooter, Models FNS01 and FNS03) have the same intended use as the legally marketed predicate device (K252349, Mojo-T330). The subject devices and the predicate share the same core design principle, safety mechanisms, and regulatory classification. All differences — including wheel configuration, device and folded dimensions, ground clearance, wheel size and type, travel distance, braking distance, operation incline, turning radius, obstacle-climbing capability, motor power, and battery configuration, as well as the Bluetooth BLE 5.0 remote-control function present in FNS01 but absent from the predicate — have been adequately addressed through design control, risk analysis, performance testing (per ISO 7176 series and EN 12184), and, for the wireless function, dedicated remote-control testing and a complete cybersecurity assessment. These differences do not affect the safety or effectiveness of the device. Accordingly, the subject devices are Substantially Equivalent to the predicate device.