June 18, 2025

Jiangxi Jiangte Electric Vehicle Co., Ltd.
Qi Ding
Manager
No.12 Chunchao Road, Economic Development Zone
Yichun, Jiangxi 336000
China

Re: K243102
Trade/Device Name: Mobility Scooter (JT10)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: May 27, 2025
Received: May 27, 2025

Dear Qi Ding:

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,

Julia E. Slocomb -S 2025.06.18 11:05:24 -04'00'

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)*

K243102

Device Name

Mobility Scooter (JT10)

Indications for Use *(Describe)*

The Mobility Scooter (Model: JT10) 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: K243102**

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

1. **Summary Prepared Date**

   20 September 2024

2. **Submitter's Information**

**Sponsor**

- Company Name: Jiangxi Jiangte Electric Vehicle Co., Ltd.
- Address: No.12 Chunchao Road, Economic Development Zone, Yichun City, Jiangxi Province, China
- Phone: 86-18897959687
- Contact Person (including title): Ms. Qi Ding (Regulatory Manager)
- E-mail: zcy_cg@163.com

**Application Correspondent:**

- Company Name: Jiangxi Jiangte Electric Vehicle Co., Ltd.
- Address: No.12 Chunchao Road, Economic Development Zone, Yichun City, Jiangxi Province, China
- Phone: 86-18897959687
- Contact Person (including title): Ms. Qi Ding (Regulatory Manager)
- E-mail: zcy_cg@163.com

3. **Subject Device Information**

- Type of 510(k) submission: Traditional
- Common Name: Motorized three-wheeled vehicle
- Trade Name: Mobility Scooter
- Model: JT10
- Classification Name: Vehicle, Motorized 3-Wheeled
- Review Panel: Physical Medicine
- Product Code: INI
- Regulation Number: 890.3800
- Regulation Class: II

4. **Predicate Device Information**

- 510(k) number: K231428
- Sponsor: Zhejiang Innuovo Rehabilitation Devices Co.,Ltd
- Trade Name: Mobility Scooter (Models:W3431D)
- Classification Name: Motorized three-wheeled vehicle

- Model: W3431D
- Review Panel: Physical Medicine
- Product Code: INI
- Regulation Number: 890.3800
- Regulation Class: II

## 5. Device Description

The Mobility Scooter, Model JT10 is intended to be used by individuals that are able to walk but suffer from mobility limitations. It has a base with steel frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, a tiller console, electric motor, electromagnetic brake, 2 rechargeable Lead-acid batteries with an off-board charger. The movement of the scooter is controlled by the rider who operates the throttle lever, speed knob 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.

## 6. Indications for Use

The Mobility Scooter (Model: JT10) 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.

## 7. Comparison to Predicate Device

Compare to the predicate devices, the subject device has same intended use, similar product design, same performance, same safety as the predicate device, the summarized comparison information is listed in the following table:

**Table 1 General Comparison**

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Manufacturer | Jiangxi Jiangte Electric Vehicle Co., Ltd. | Zhejiang Innuovo Rehabilitation Devices Co.,Ltd | - |
| Product Code | INI | INI | Same |
| Regulation No. | 21 CFR 890.3800 | 21 CFR 890.3800 | Same |
| Class | II | II | Same |
| Product name | Mobility Scooter | Scooter | - |
| 510 (k) Number | - | K231428 | - |
| Models | JT10 | W3431D | - |
| Intended 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 | 1080 mm x 505 mm x 870 mm | 90cm x59cm x99cm | Different Note 1 |
| Frame Material | Steel | Steel | Same |
| Frame Style | Foldable seat, removable battery pack, disassemble for transport | Foldable seat, removable battery pack, disassemble for transport | Same |
| Front wheel size | 230mm | 190 x 55 mm | Different Note 1 |
| Front wheels Quantity | 2 | 2 | Same |
| Rear wheel size | 230mm | 190 x 55 mm | Different Note 1 |
| Rear wheels Quantity | 2 | 2 | Same |
| Ground clearance | 65mm | 45 mm | Different Note 2 |
| Max Loading( on level ground) | 136kg | 120kg | Different Note1 |
| Turn Radius | 1700mm | 1650mm | Different Note 3 |
| Motor output | 300W, 24V | 180W, 24V | Different Note 4 |
| Drive System | Rear Wheel Drive | Rear Wheel Drive | Same |
| Brakes | Electromagnetic brake | Electromagnetic brake | Same |
| Battery | Lead acid 12V 20Ah *2 | Lead-acid 12V12Ah*2 | Different Note 5 |
| Charger | 24V/2A | 24V/2A | Same |
| Max Speed | 5.79 km/h | 6 km/h | Different Note 7 |
| Slope Grade Ability | 6 degree | 9 degree | Different Note 6 |
| Travel Distance | 25km/15.53 Miles | 15 km/9.32 Miles | Different Note 7 |

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Arm Rests (Distance between armrests) | 42cm | 44-56 cm | Different Note 1 |
| Controller | PG45A | PG45A | Same |
| Time to brake | 1s | 0.7-1s | Different Note 8 |
| Brake Distance-Normal operation (Horizontal-Forward-Max speed) | 0.8 m | ≤1.5m | Different Note 8 |
| Battery weight | 12kg | 8.8kg | Different Note 5 |
| Base weight (not including battery) | 48kg | 42kg | Different Note 1 |
| Operating surface & environment | Indoor and outdoor use | Indoor use and restricted outdoor use on pavements or paved footpaths only. | Same |
| Remote control | None | None | Same |

**Note 1**
Compared to the predicate device, the subject device has different value on the overall dimensions, Max Loading, weight, Arm Rests(Distance between armrests) and tire size, and the subject device has passed the requirements of standard ISO 7176 series, so there are no any new safety and effectiveness concerns raised by subject device.

**Note 2**
The ground clearance for the predicate device is 45mm and it is 65mm for the subject device. So, there are less limitations for the subject device than the predicate device when moving across an obstruct. There are no any new safety and effectiveness concerns raised by subject device.

**Note 3**
Subject Device has a 1700mm turning radium, while the predicate device has a 1650mm turning radium. The subject device has passed the requirements of standard ISO 7176-5:2008 The difference will not raise any new safety and effectiveness concerns.

**Note 4**
The motor types for both devices are different. The predicate device uses motor of 180W / 24 Vdc, and the subject device uses motor of 300 W /24 Vdc. But the motor used in the subject device passed the requirements of the EMC standards: ISO 7176-21:2009, and performance standards: ISO 7176-14:2008. So, there are no any new safety and effectiveness concerns raised due to different motor used by the subject devices.

**Note 5**
The battery ratings for both devices are different. The predicate device uses two Lead acid batteries rating at 12 Vdc, 12 Ah, and the subject device used two Lead acid batteries

rating at 12 Vdc, 20 Ah. The total weight of batteries of predicate device is 8.8kg, and the weight of batteries of subject device is 12kg.
The battery for the subject device has passed the requirements of ISO 7176-14:2008, so there are no any new safety and effectiveness concerns raised by subject device.

**Note 6**
The Slope Grade Ability for the predicate device is 9 degree and it is 6 degree for the subject device. A smaller Slope Grade Ability will not lead to dangerous situations, this will not affect the use of the product function and safety. And the subject device has passed the requirements of standard ISO 7176-2:2017, so there are no any new safety and effectiveness concerns raised by subject device.

**Note 7**
The Travel Distances for the predicate and the subject devices are 15 km and 25km. The maximum speed for the predicate and the subject devices are 6.0 km/h and 5.79 km/h The difference of the travel Distance and maximum speed will not raise any new safety and effectiveness concerns for the subject device.

**Note 8**
Compared to the predicate device, the subject device has different value on time to brake and brake Distance, and the subject device has passed the requirements of standard ISO 7176-3:2012, so there are no any new safety and effectiveness concerns raised by subject device.

## Table 2 Safety comparison

| Item | Subject Device | Predicate Devices | Verdict |
|---|---|---|---|
| Biocompatibility | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | Same |
| EMC | ISO7176-21 | ISO7176-21 | Same |
| Performance | ISO7176 series | ISO7176 series | Same |
| Label and labeling | Conforms to FDA Regulatory | Conforms to FDA Regulatory | Same |

## Table 3 Safety comparison

| Item | Subject Device | Predicate Devices | Verdict |
|---|---|---|---|
| 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 | ~ |
| 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 | Same |
| ISO7176-3 | The effectiveness of brakes has been determined after the | The effectiveness of brakes has been determined after the testing | Same |

| | | | |
|---|---|---|---|
| | testing according to the ISO 7176-3, and test results meet its design specification. | according to the ISO 7176-3, and test results meet its design specification. | |
| ISO7176-4 | The theoretical distance range has<br>been determined after the testing<br>according to the ISO 7176-4, and test results meet its design specification | The theoretical distance range has<br>been determined after the testing according to the ISO 7176-4, and test results meet its design specification | Same |
| ISO7176-5 | The dimensions, mass have been<br>determined after the testing according to the ISO 7176-5 | The dimensions, mass have been<br>determined after the testing according to the ISO 7176-5 | Same |
| ISO7176-6 | The maximum speed has been determined after the testing according to the ISO 7176-6 | The maximum speed has been determined after the testing according to the ISO 7176-6 | Same |
| ISO7176-7 | The seating and wheel dimensions<br>has been determined after the testing according to the ISO 7176-7. | The seating and wheel dimensions<br>has been determined after the testing according to the ISO 7176-7. | Same |
| ISO7176-8 | All test results meet the requirements in Clause 4 of ISO 7176-8 | All test results meet the requirements in Clause 4 of ISO 7176-8 | Same |
| ISO7176-9 | The test results shown that the device under tests could continue to<br>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<br>function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9 | Same |
| ISO7176-10 | The obstacle-climbing ability of device has been determined after the<br>testing according to the ISO 7176-10 | The obstacle-climbing ability of device has been determined after the<br>testing according to the ISO 7176-10 | Same |
| ISO7176-11 | The test dummies used in the testing<br>of ISO 7176 series are meet the<br>requirements of ISO 7176-11 | The test dummies used in the testing<br>of ISO 7176 series are meet the requirements of ISO 7176-11 | Same |
| 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 | Same |
| 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 | Same |
| ISO7176-15 | The test results shown that information disclosure, documentation and labelling of device meet the requirements of<br>ISO 7176-15 | The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15 | Same |
| ISO7176-16 | The performance of resistance to ignition meet the requirements of ISO 7176-16 | The performance of resistance to ignition meet the requirements of ISO 7176-16 | Same |
| ISO7176-21 | The EMC performance results | The EMC performance results | Same |

| | | | |
|---|---|---|---|
| | meet the requirements of ISO 7176-21 | meet<br>the requirements of ISO 7176-21 | |
| ISO7176-25 | The performance of batteries and<br>charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25 | The performance of batteries and<br>charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25 | Same |

**8. Non-clinical data**

The Mobility Scooter has been evaluated the safety and performance by lab bench testing according to 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 7176-16: 2012 Wheelchairs - Part 16: Resistance to ignition of postural support devices
• ISO 7176-22:2014 Wheelchairs —Part 22:Set-up procedures
• ISO 7176-25 2013 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.

EMC
• ISO 7176-21: 2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.
• IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

Biocompatibility
• ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
• ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
• ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization
• ISO 10993-23:2021 Biological evaluation of medical devices —Part 23:Tests for irritation
All contact materials have passed biological tests and are harmless to humans

FDA software validation guidance “General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002”.
FDA guidance: Content of Premarket Submissions for Device Software Functions, JULY 20, 2023

**Clinical test**
Clinical testing was not performed on the device.

## 9. Conclusion

In conclusion, 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. From the results of nonclinical testing described, it can be concluded that the Mobility Scooter, Model: JT10 is substantially equivalent to the legally marketed predicate device cleared under K231428.