January 29, 2026

Dongguan Smarfody Mobility Technology Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K252347
Trade/Device Name: Electric Scooter (Mojo-T580)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: July 29, 2025
Received: July 29, 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

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.

510(k) Number *(if known)*
K252347

Device Name
Electric Scooter (Mojo-T580)

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting 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.

510(K) Summary

Application Information:
Dongguan Smarfody Mobility Technology Co.,Ltd.
Address: Room 202, Building2, No.9 Junpu Industry 1st Road, Houjie Town, Dongguan City, Guangdong Province, P.R. China
Telephone Number: 0086 13798786794
Contact Person: Alex Wu

Device Name： Electric Scooter
Model: Mojo-T580
Classification: II
Product Code: INI
Regulation:890.3800
Panel: Motorized three-wheeled vehicle

Date Prepared： Jan 27,2026

Predicate Device
510Knumber: K232692
Device Name: Powered Mobility Scooter
Model: PMS101, GUT112, PMS103, GUT140
Manufacturer: Intradin (Shanghai) Machinery Co., Ltd

Indication for use: The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Patient Population: Adult only

1. Device Description

The Electric Scooter, has a base with metal frame, two front wheels, two rear wheels, a seat, a LCD Display, electric motor, electromagnetic brake, 1 rechargeable Lithium Battery with an off-board charger. The movement of the scooter is controlled by the rider who operates the control lever, speed control turn “speed” Knob. 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 surface. The device can be folded from up to down by manual.

2. Comparison with Predicate Device

Table 1 General Comparison

Elements of Comparison	Subject Device	Predicate Device (K232692)	Remark
Manufacturer	Dongguan Smarfody Mobility Technology Co., Ltd.	Intradin (Shanghai) Machinery Co., Ltd.	NA
Device name	Electric Scooter	Powered Mobility Scooter	NA
Model(s)	Mojo-T580	PMS101	NA
Product Code	INI	INI	Same
Device Classification Regulation	890.3800	890.3800	Same
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.	Same
Number of Wheels	4	3	Similar
Overall dimension (Length x Width x Height)	1030mm x 530mm x 960mm	1025mm x 595mm x 940mm	Similar
Folded Dimensions (Length x Width x Height)	1000mm x 440mm x 385mm	640mm x 595mm x 405mm	Similar

Front wheel size	~7" (175 x 40 mm)	170 x 45 mm	Similar
Rear wheel size	~7" (175 x 40 mm)	170 x 45 mm	Similar
Maximum load	125kg	125kg	Same
speed (forward)	6.12km/h	5.0km/h	Similar
Battery	Lithium-ion Battery 25.9V/10.4AH/269Wh	44.4V 2.0 Ah Lithium-ion Battery	Similar
Charger	Input: AC 100-240V, 50/60Hz, 1.5A. Output: 29.4V, 2.0A	Input: AC 100-240V, 50/60Hz, 3A. Output: 50.4V, 1A	Similar
Maximum Travel distance	11.7km	15.6km	Similar
Type of controller	Brushless DC Motor Controller 24V	Brushless DC Motor Controller Nominal Battery Voltage: 48V Current Limit: 18±1A	Similar
Motor	24V/200W, Brushless electric motor	48 volt DC, Brushless electric motor with 3 phases & sensors	Similar
Total mass	17kg	18kg	Similar
Turn radius	1500mm	1500mm	Same
Dynamic Stabilities	3°	3°	Same
Static Stabilities	Uphill:25° Downhill: 15.7° Sideways:12.1°	Uphill： Least stable configuration: 20.8° Most stable configuration: 22.0° Sideway: Left 11.8°, Right 12.2°	Similar
Obstacle Climbing Ability (max)	20mm	20mm	Same
Braking distance from max speed (Forward Horizontal)	1200mm	500mm	Similar

Analysis: Subject device control system has passed the requirements of ISO 7176 series and test results meet its design specification. Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (S.E.) to the predicate device.

Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO 10993-1	All user directly contacting materials are compliance with ISO 10993-5, ISO 10993-10, and ISO 10993-23 requirements	S.E.
EMC	ISO7176-21& IEC 60601-1-2:2014+A1:2020	ISO7176-21& IEC 60601-1-2	S.E.

Performance	ISO7176 series	ISO7176 series	S.E.
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	S.E.

Item	Proposed Device	Predicate Device	Results
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.	S.E.
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.	S.E.
ISO7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet its design specification.	S.E.
ISO7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet its design specification.	S.E.
ISO7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	S.E.
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,	S.E.
ISO7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	S.E.
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	S.E.
ISO7176-9	The test results shown that the device under tests could continue to 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 function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	S.E.
ISO7176-10	The obstacle-climbing ability of device has been determined after the	The obstacle-climbing ability of device has been determined after	S.E.

	testing according to the ISO 7176-10,	the testing according to the ISO 7176-10,	
ISO7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	The test dummies used in the testing of ISO 7176 series are meet the requirements of ISO 7176-11	S.E.
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	S.E.
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	S.E.
ISO7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	S.E.
16840-10	The performance of resistance to ignition meet the requirements of 16840-10	The performance of resistance to ignition meet the requirements of 16840-10	S.E.
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21, IEC 60601-1-2:2014+A1:2020	The EMC performance results meet the requirements of ISO 7176-21, IEC 60601-1-2:2014+A1:2020	S.E.
	The performance of batteries and charger of device meet the Requirements of ISO 7176-31 and IEC 62133-2	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	S.E.

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 16840-10, and IEC 62133-2 and FDA guidance 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.

3. Substantially Equivalency Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices, Powered Mobility Scooter from Intradin (Shanghai) Machinery Co., Ltd under K232692.