November 21, 2025

Intradin (Shanghai) Machinery Co., Ltd
℅ Ariel Xiang
Senior Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai, 200122
China

Re: K252590
Trade/Device Name: Powered Mobility Scooter (PMS105, GUT177, GCAT047)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: September 30, 2025
Received: September 30, 2025

Dear Ariel Xiang:

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

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)*

K252590

Device Name

Powered Mobility Scooter (PMS105, GUT177, GCAT047)

Indications for Use *(Describe)*

The Powered Mobility scooter 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Intradin (Shanghai) Machinery Co., Ltd
No. 118, Duhui Road, Minhang District, Shanghai,

510(K) Summary

K252590

Document Prepared Date: 2025/11/10

A. Applicant:

Intradin (Shanghai) Machinery Co., Ltd

Address: No. 118, Duhui Road, Minhang District, Shanghai, China

Contact Person: Mark Li

Tel: + 86 021-64908190-6665

Submission Correspondent:

Primary contact: Ms.Ariel Xiang

Shanghai SUNGO Management Consulting Co., Ltd.

14th Floor, Dongfang Building, 1500# Central Ave., Shanghai 200122, China

Tel: +86-21-58817802

Email:shouqiu.xiang@sungoglobal.com

B. Device:

Trade Name: Powered Mobility Scooter

Common Name: Scooter

Model :GUT177,MS105, GCAT047

Regulatory Information

Classification Name: Motorized three-wheeled vehicle

Classification: Class II.

Product code: INI

Regulation Number: 890.3800

C. Predicate device:

510(K) number: K250027

Trade Name: Powered Mobility Scooter

Common Name: Scooter

Model: GUT164,GUT165,PMS104,GCAT040

D. Indication for use

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

E. Device Description

The Powered Mobility Scooter, Model PMS105, GUT177, GCAT047 is mainly composed of frame,two front wheel,two drive wheel,control system,motor and drive device, ,armrest,backrest,seat cushion,pedal,battery and charger.

The traveling speed is controlled by the motor, and the traveling direction is manually controlled by the accompanying personnel or passengers. 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.When encountering an obstacle in front, please make a detour to avoid the danger of overturning the scooter.It has a driving range of 9.2 km between charges. It is capable of carrying a driver weighing up to 150kg.

F. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device	Results
Manufacturer	Intradin (Shanghai) Machinery Co., Ltd	Intradin (Shanghai) Machinery Co., Ltd	/
Common or Usual name	Scooter	Scooter	/
Model(s)	GUT177,MS105, GCAT047	GUT164,GUT165,PMS104,GCAT040	/
510(k) number	K252590	K250027	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3800	21 CFR 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	4	Same
Overall Dimensions (Length*Width*Height)	1060mm x 590mm x 930mm	1040mm x 610mm x 970mm	Similar **Analysis:** The predicate device and proposed device have

			different dimensions. Both comply with ISO
Folded Dimensions(Length*Width* Height)	980mm x 550mm x 320mm	1020mm x 610mm x 310mm	7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness
Front wheel size	170 x 45 mm	170 x 45 mm	Same
Rear wheel size	170 x 45 mm	170 x 45 mm	Same
Maximum load	150KG	150KG	Same
Maximum speed (forward)	1.9 m/s	2.0m/s(7.2km/h)	Similar,**Analysis:** Minor difference on maximum speed forwarding speed will not cause different performance. The speed is limited to the regulatory standards required by the FDA.
Travel distance	9.2 km	9.8 km	Similar,**Analysis:** The subject device complies with ISO 7176- 4: 2008 Wheelchairs -Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range, these differences do not affect safety and effectiveness.

Scooter Weight with Battery	23kg	24kg	Similar,**Analysis:** The predicate device and Proposed device have different weight..Both comply with ISO 7176-5:2008 Wheelchairs– Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness
Turn diameter	2700mm	2125mm	**Similar,Analysis:** Larger turning radius will bring more convenience for the use environment.All relevant tests have been performed according to standards ISO 7176 series, the difference will not raise any new safety and effectiveness concerns.
Dynamic Stability	6°	6°	Same
Static Stability	Downhill:＞25.0° Uphill：Min23.1°,Max:27.1° Side way:Left 15.0°,Right15.8°	Downhill:Min36.1°,Max:40.0° Uphill：Min26.5°,Max:29.8° Side way:Left 13.5°,Right 16.5°	**Similar,Analysis:** The Proposed device has better stability.Proposed device control system has passed the requirements of ISO 7176-1 and test results meet its design specification..
Ground clearance	25mm	72mm	**Similar,Analysis:** The predicate device and proposed device have

			different ground clearance. Both comply with ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass, and maneuverings space so these differences do not affect safety and effectiveness.
Kerb Climbing Ability	15mm	5mm	**Same,**The Proposed device complies with the requirements of ISO 7176-10.
Braking distance from max speed	Forwards1.1m ,Reverse 0.4m	Forwards 0.8m ,Reverse 0.2m	**Similar,Analysis:** The proposed device complies with the requirements of ISO 7176-3.
Battery	44.4V 2.0 Ah Lithium-ion Battery	44.4V 2.0 Ah Lithium-ion Battery	Same
Charger	Input: AC 100-240V, 50/60Hz, 2.5A. Output: 50.4V, 1A	Input: AC 100-240V, 50/60Hz,2.5A. Output: 50.4V, 1A	Same
Controller	48V,18±1A	BLDC MOTOR CONTROLLER,48V18A	Same
Motor	48VDC /250W	DC Brushless motor 48VDC /300W	Analysis: Compared to the Predicate device, the proposed Model 2 device is identical, whereas Model 1 is different.

			The proposed device's power and control system has successfully met the criteria set forth in ISO 7176-14:2008 and has undergone rigorous software validation, confirming its performance is indeed validated. The difference between the predicate and proposed devices does not introduce any new safety or effectiveness concerns for the subject device.

Table 2 safety comparison

Item	Proposed Device	Predicate Device	Results
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 ,ISO10993-10, ISO10993-23 requirements and FDA Guidance.	All user directly contacting materials are compliance with ISO10993-5 ,ISO10993-10, ISO10993-23 requirements and FDA Guidance.	SE
EMC	IEC 60601-1-2 & IEC TS 60601-4-2	ISO 7176-21&IEC 60601-1-2&IEC TR 60601-4-2	SE
Performance	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 16840-10,ISO 7176-21, ISO 7176-22,ISO 7176-25, ISO 7176-31	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 16840-10,ISO 7176-21, ISO 7176-22,ISO 7176-25	SE
Battery Safety	IEC 62133-2	IEC 62133-2	SE
Software Verification	IEC 62304 &FDA Guidance	IEC 62304 &FDA Guidance	SE
Label and labeling	Conforms to FDA Regulatory	Conforms to FDA Regulatory	SE

G. 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 16840-10,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.

H. Non-Clinical Test summary

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO10993-5 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation

- From the test result, we can find the material are safety and can meet the requirements.
- 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 proceduresd
- ISO 7176-25：2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs.

- ISO 7176-31:2023 Wheelchairs-Part 31: Lithium-ion battery systems and chargers for powered wheelchairs —Requirements and test methods.
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020 and IEC TS 60601-4-2:2024
- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software-Software life cycle processes
- IEC 62133-2 dition1.0 2017-02 Secondary cells and batteries containing alkaline or other non- acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems

I. 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.

J. Substantially Equivalency Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the proposed device Powered Mobility Scooter,is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K250027.