September 5, 2024

Intradin (Shanghai) Machinery Co., Ltd
% Ariel Xiang
Senior Consultant
Shanghai Sungo Management Consulting Company Limited
14th floor, 1500# Century Ave
Shanghai, Shanghai 200122
China

Re: K232692
Trade/Device Name: Powered Mobility Scooter (Models: PMS101, GUT112, PMS103, GUT140)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: August 9, 2024
Received: August 9, 2024

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
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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)*

K232692

Device Name

Powered Mobility Scooter (Models: PMS101, GUT112, PMS103, GUT140)

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.

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

510(K) Summary

K232692

Document Prepared Date: 2024/09/03

A. Applicant:

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B. Device:

Trade Name: Powered Mobility Scooter
Common Name: Scooter

Models: PMS101, GUT112, PMS103, GUT140

Regulatory Information

Classification Name: Motorized three-wheeled vehicle
Classification: Class II.

Product code: INI

Regulation Number: 890.3800

Review Panel: Physical Medicine

C. Predicate device:

510Knumber: K220227

Device Name: Auto Folding Scooter, S21F

Manufacturer: Heartway Medical Products Co., Ltd.

D. Indications for use of the device:

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

E. Device Description:

The Powered Mobility Scooter, Models: PMS101, GUT112, is a battery powered three wheeled scooter intended to provide mobility for elderly or disabled individuals in a variety of indoor and outdoor settings. It consists lithium battery with an off-board battery charger, Handle-bar, Brake, Seat, Back support, Frame, One Front wheel and Two Rear wheels.

The scooter controlled through a thumb throttle. The left brake handle is controlled mechanical brake which lock the drum brake in the right rear wheel. When actuated brake handle, it will stop scooter and cut power supply to the motor .It has a driving range of 15.6 km between charges. It is capable of carrying a driver weighing up to 125 kg.

Note: The Powered Mobility Scooter, Model PMS101 and GUT112 are identical devices, two different model numbers are for sale purpose.

The Powered Mobility Scooter, Models: PMS103, GUT140, is a battery powered three wheeled scooter intended to provide mobility for elderly or disabled individuals in a variety of indoor and outdoor settings. It consists lithium battery with an off-board battery charger, Handle-bar, Brake, Seat, Back support, Frame, Armrest, One Front wheel and Two Rear wheels.

The scooter controlled through a thumb throttle. The left brake handle is controlled mechanical brake which lock the drum brake in the right rear wheel. When actuated brake handle, it will stop scooter and cut power supply to the motor. It has a driving range of 10.4 km between charges. It is capable of carrying a driver weighing up to 125 kg.

Note: The Powered Mobility Scooter, Model PMS103 and GUT140 are identical devices, two different model numbers are for sale purpose.

The model PMS101/GUT112 and PMS103/GUT140 mobility scooter power control systems and related components(controller, motor, battery, charger) are identical.

Note: The dynamic stability rating of 3° applies to braking while traveling straight on an inclined surface.
WARNING – Do not use maximum speed while making turns, as the scooter is not stable under these conditions and may tip over, causing a risk injury.

F. Non-Clinical Test Conclusion

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:

- 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
- ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017, Wheelchairs - Part 2: Determination of dynamic stability of Powered Wheelchairs
- ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness ofbrakes

- ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption ofelectric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5, Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space
- ISO 7176-6: 2018, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of Powered Wheelchairs
- ISO 7176-7, 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 Powered 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, First edition 1989-08-01, 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
- ISO16840-10: 2021Wheelchair 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, and battery chargers
- ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020 (including clause 8.11), plus immunity testing to 5G cellular signals.

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate Device

Table 1 General Comparison

Elements of Comparison	Predicate Device (K220227)	Subject Device	Results
Manufacturer	Heartway Medical Products Co., Ltd.	Intradin (Shanghai) Machinery Co., Ltd	/
Common or Usual name	Auto Folding Scooter, S21F	Scooter	/
Model(s)	S21F	PMS101, GUT112, PMS 103, GUT140	/
510(k) number	K220227	K232692	/
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	3	Similar
Overall Dimensions (Length*Width* Height)	840mm x 460mm x 770mm	Model PMS101 & GUT112: 1025mm x 595mm x 940mm Model PMS103 & GUT140: 1080mm x 600mm x 420mm	Similar **Analysis:** The predicate device and subject device have different dimensions. 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
Folded Dimensions (Length*Width* Height)	730mm x 440mm x 420mm	Model PMS101 & GUT112: 640mm x 595mm x 405mm Model PMS103 & GUT140: 670mm x 600mm x 490mm	
Front wheel size	7” x 1.6” (178 x41 mm)	Model PMS101 & GUT112: 170 x 45 mm Model PMS103 & GUT140: 195x 50 mm	Similar, **Analysis:** Different sizes of wheel will not affect safety and performance of the subject device as all related stability tests are performed according to standard ISO 7176 series.
Rear wheel size	8” x 2” (203x 51mm)	Model PMS101 & GUT112: 170 x 45 mm Model PMS103 & GUT140:	

		200 x 50 mm	
Maximum load	115kg	125kg	Similar, **Analysis:** Minor difference on Maximum load will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Maximum speed (forward)	6km/h	5.0km/h	**Analysis** Minor difference on max. forwarding speed will not cause different performance. Lower speed will be more safety
Battery	One 25.2 Vdc, 11.5 Ah Lithium-ion Battery	44.4V 2.0 Ah Lithium-ion Battery	Similar, **Analysis:** The subject device complies with ISO 7176- 25: 2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs and EMC testing, these differences do not affect safety and effectiveness.
Charger	AC input.110-240 v, 50/60Hz, 84w Output29.05V,2.5A	Input: AC 100-240V, 50/60Hz, 3A. Output: 50.4V, 1A	
Travel distance	15 km	Model PMS101&GUT112: 15.6km Model PMS103 & GUT140: 10.4 km	**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.
Type of controller	Dynamic, R series, DR50	Brushless DC Motor Controller Nominal Battery Voltage: 48V Current Limit: 18±1A	**Analysis :** Subject device control system has passed the requirements of ISO 7176-14:2008 and software validation, its performance is surely validated. The differences of the electronic controller's naming by the predicate and subject devices will not raise any new safety and effectiveness concerns for the subject device
Motor	2.5 A max, 24 Vdc, 180 W	48 volt DC, Brushless electric motor with 3 phases & sensors	
Scooter Weight with Battery	51.8 Ibs. (23.5 kg)	PMS101&GUT112: 18kg	Analysis: The predicate device and subject

		PMS103 &GUT140: 24kg	device havedifferent 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 radius	1110mm	Model PMS101 & GUT112: 1500mm Model PMS103 & GUT140: 1550 mm	**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 Stabilities	3°	Model PMS101 & GUT112: 3° Model PMS103 & GUT140: 5°	Model PMS101 &GUT112: Same Model PMS103 &GUT140: **Analysis:** Greater dynamic stability usually means that the vehicle is safer and more reliable while driving.Subject device control system has passed the requirements of ISO 7176-2 and test results meet its design specification.
Static Stabilities	6°	Tipping Angles: Model PMS101 & GUT112: Uphill： Least stable configuration: 20.8° Most stable configuration: 22.0° Sideway: Left 11.8°, Right 12.2° Model PMS103 & GUT140: Uphill： Least table tipping angle: 18.8°, Most stable tipping angle: 20.4° Sideway: Left 13.1°, Right 12.8°	**Analysis:** Subject device control system has passed the requirements of ISO 7176-1 and test results meet its design specification..
Ground clearance	30 mm	Model PMS101 & GUT112: 67mm Model PMS103 & GUT140: 82mm	**Analysis**: The predicate device and subject 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
Obstacle Climbing Ability (max)	15mm	Forward: Model PMS101 & GUT112: 20mm Model PMS 103 & GUT140: 25 mm Reverse: 5mm	The subject device complies with the requirements of ISO 7176-10.
Braking distance from max speed	N/A	Forward： 0.5m Reverse: Model PMS101&GUT112: 0.3m Model PMS103 &GUT140: 0.2m	The subject device complies with the requirements of ISO 7176-3

Table 2 Safety comparison

Item	Predicate Devices	Subject Device	Results
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 ,ISO10993-10 and ISO10993-23 requirements.	S.E.
EMC	ISO7176-21	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.

Table 3 Safety comparison

Item	Proposed Device	Predicate Device	Results
ISO 7176-1	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.	SE
ISO 7176-2	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.	SE
ISO 7176-3	The effectiveness of brakes has been	The effectiveness of brakes has been	SE

	determined after the testing according to the ISO 7176-3, and test results meet its design specification.	determined after the testing according to the ISO 7176-3, and test results meet its design specification.	
ISO 7176-4	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.	SE
ISO 7176-5	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,	SE
ISO 7176-6	The dimensions, mass has been determined after the testing according to the ISO 7176- 6,	The dimensions, mass has been determined after the testing according to the ISO 7176- 6,	SE
ISO 7176-7	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,	SE
ISO 7176-8	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	SE
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	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	SE
ISO 7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	SE
ISO 7176-11	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	SE
ISO 7176-13	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	SE
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	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	SE
	The test results shown that information	The test results shown that information	

ISO 7176-15	disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	SE
ISO 16840-10	The performance of resistance to ignition meet the requirements of ISO16840-10.	The performance of resistance to ignition meet the requirements of ISO 7176-16	SE
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	SE
ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	SE

I. 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.

J. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Powered Mobility Scooter, Models: PMS101, GUT112, PMS103, GUT140, is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K220227.