



March 17, 2026

Lerado Zhongshan Peaceful Cove Business Trading Co., Ltd.
Ke-Min Jen
Primary Contact
No. 26, Guangfu Road, Xiaolan Town
Zhongshan, Guangdong 528414
China

Re: K252813
Trade/Device Name: Electrical Scooter (SM4226)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: February 9, 2026
Received: February 9, 2026

Dear Ke-Min Jen:

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 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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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

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

Indications for Use

510(k) Number (if known)

K251813

Device Name

Electrical Scooter, SM4226

Indications for Use (Describe)

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.

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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LERADO ZHONGSHAN PEACEFUL COVE BUSINESS TRADING CO., LTD.

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510(k) Summary (21 CFR 807.92)

Submitter's name: Lerado Zhongshan Peaceful Cove Business Trading Co., Ltd.
Summary prepared date: February 14, 2026
Common or usual name: Electrical Scooter
Classification name: Motorized Three-Wheeled Vehicle
Class II, 21 CFR 890.3800
Review Panel: Physical Medicine
Product code: INI
Trade name: Electrical Scooter, SM4226
Contact Person: Jen, Ke-Min, Ph.D.
Email: ceirs.jen@msa.hinet.net
TEL: 886-3-5208829
Predicate device: Zhejiang Innuovo Rehabilitation Devices Co., Ltd.
Mobility Scooter, W3431
510(k) number: K240012

● **Indications for 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.

● **Device Description:**

Electrical Scooter, SM4226, is for indoor or outdoor uses, and it is powered by two 12 Ah sealed Lead-acid batteries with an off-board charger and configured with 4 PU solid wheels, 2 anti-tip wheels, a seat, a turning tiller, aluminum alloy main frame and a control panel.

SM4226 is driven by two PU solid rear wheels (7.48" x 2.16") and steered by two PU solid front wheels (7.48" x 2.16"). The user can control the turning tiller to control the front wheels to steer the scooter's direction. The movement of the scooter is controlled by the rider who operates the throttle lever to drive forward or backward, speed adjustment knob and handles on the turning tiller. Release the throttle lever completely and the electromagnetic brake installed in the motor will be activated automatically, and the scooter will stop. There are two anti-tip wheels to prevent the tipping hazard.



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The maximum weight capacity is 297 lbs. (135 kg). Its maximum forward speed is 4 mph (6.4 km/h), and its maximum safe climbing incline angle is 6 degrees. The cruising range per charge is 6.875 miles (11 km). There is a storage basket affixed to the turning tiller.

The following surfaces are recommended NOT to operate on:

- ☐ Sand surface
- ☐ Wet or icy surface
- ☐ Road maintenance hole metal cover
- ☐ Avoid going up multiple steps.
- ☐ Avoid using escalators. Use the elevator.
- ☐ Too steep incline over 6 degrees.
- ☐ Obstacle climbing ability over 1.96"/ 50 mm
- ☐ Ground clearance below 1.96"/50 mm

● **Non-clinical performance tests**

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

- ✓ 2-245 ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ✓ 2-296 ISO 10993-10: 2021 Biological evaluation of medical devices -- Part 10: Tests for skin sensitization
- ✓ 2-291 ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
- ✓ 19-49 IEC 60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical Electrical Equipment Part 1: General Requirement for Basic Safety and Essential Performance
- ✓ 19-36 IEC 60601-1-2: 2014/AMD1: 2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- ✓ 16-195 ISO 7176-1: 2014 Wheelchairs - Part 1: Determination of static stability
- ✓ 16-202 ISO 7176-2: 2017 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs



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- ✓ 16-192 ISO 7176-3: 2013 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ✓ 16-162 ISO 7176-4: 2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range,
- ✓ 16-163 ISO 7176-5: 2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering space,
- ✓ 16-204 ISO 7176-6: 2018 Wheelchairs - Part 6: Determination of maximum speed of electrically powered wheelchairs
- ✓ 16-196 ISO 7176-7: 1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- ✓ 16-197 ISO 7176-8: 2014 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- ✓ 16-167 ISO 7176-9: 2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- ✓ 16-164 ISO 7176-10: 2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ✓ 16-190 ISO 7176-11: 2012 Wheelchairs - Part 11: Test dummies
- ✓ 16-25 ISO 7176-13 First edition 1989-08-01 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- ✓ 16-234 ISO 7176-14: 2022 Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- ✓ 16-27 ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- ✓ 16-233 ISO 16840-10 Second edition 2021-06 Corrected version 2022-01 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method
- ✓ 16-198 ISO 7176-22: 2014 Wheelchairs – Part 22: Set-up procedures
- ✓ 16-235 ISO 7176-25 Second Edition 2022 Wheelchairs - Part 25: Lead-acid batteries and chargers for powered wheelchairs - Requirements and test methods



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● **Comparison table**

Devices Specifications	Subject device	Predicate device	Comparison results
Manufacturer	Lerado Zhongshan Peaceful Cove Business Trading Co., Ltd.	Zhejiang Innuovo Rehabilitation Devices Co., Ltd.	--
Proprietary name	Electrical Scooter	Mobility Scooter	--
Model name	SM4226	W3431	--
510(k) No.	K252813	K240012	--
Same or Similar items			
Indications for 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 dimensions			Similar
Length	40.1" (1020 mm)	40.1" (1020 mm)	
Width	19.7" (500 mm)	19.7" (500 mm)	
Height	36.8" (935 mm)	33.0" (840 mm)	
Seat width	16.9" ~ 21.3" (430 ~ 540 mm)	17.3" ~ 22.0" (440 ~ 560 mm)	Similar
Battery	Two Lead-acid batteries Weight: 8.5 kg Model: CB12-12 Rating: 2×12 V, 12 Ah	Two Lead-acid batteries Weight: 8.8 kg Model: Long Way Rating: 2×12 V, 12 Ah	Similar
Battery Charger	Model: HP0060W(B) Input: 100-240 VAC, 50/60 Hz, 1.2-0.5 A, Output: 24 V / 2 A, Off-board type	Input: 100~240 VAC, 50/60 Hz Output: 24 V / 2 A, Off-board type	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same



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Brake System	Electromagnetic brake	Electromagnetic brake	Same
Controller	PG S-Drive 45A	PG S-Drive 45A	Same
Anti-tip wheels	Yes	Yes	Same
Max Speed (Forwards)	4 mph (6.4 km/h)	3.75 mph (6.0 km/h)	Similar
Use environments	Indoor / outdoor	Indoor/ outdoor	Same
Front wheel size & type	7.48" x 2.16" (190 x 55 mm) PU Solid tire x 2	7.48" x 2.16" (190 x 55 mm) PU Solid tire x 2	Same
Rear wheel size & type	7.48" x 2.16" (190 x 55 mm) PU Solid tire x 2	7.48" x 2.16" (190 x 55 mm) PU Solid tire x 2	Same
Manual folding	Yes	Yes	Same
Different items			
Motor	270 W, 24 V, 3.3 A max, Brush motor	LINIX 180 W, 24V	Different
Main frame material	Fixed / Aluminum alloy	Fixed / Steel	Different
Maximum safe climbing incline angle	6 degrees	9 degrees	Different
Scooter weight without battery	73.7 lbs. (33.5 kg)	92.4 lbs. (42 kg)	Different
Cruising range	6.8 miles (11 km)	9.32 miles (15 km)	Different
Max loading	297 lbs. (135 kg)	264 lbs. (120 kg)	Different
Turning radius	45.2" (1150 mm)	64.9" (1650 mm)	Different
Maximum obstacle climbing ability	1.96" (50 mm)	1.58" (40 mm)	Different
Ground clearance	1.96" (50 mm)	1.77" (45 mm)	Different



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- **Substantial equivalence discussions**

We do not discuss the items same or similar in this substantial equivalence discussion section. We discuss the items different, i.e., Motor, Main frame material, Maximum safe operational incline, Scooter weight (without Battery), Cruising range, Max loading, Turning radius, Maximum obstacle climbing ability and Ground clearance.

Motor: it is 270 W for the subject device and 180 W for the predicate device. The more power can provide more energy per second to the driven rear wheel, thus leading to have a larger maximum weight loading and larger maximum obstacle climbing ability for the subject device. This difference of the motor power is not to raise any new safety and effectiveness concerns for the subject device.

Main frame material: The subject device uses aluminum alloy and the predicate device uses steel. This leads to smaller total scooter weight without battery 73.7 lbs. for the subject device than the predicate device 92.4 lbs. There are no new safety and effectiveness concerns raised for the subject device.

Maximum safe climbing incline angle: It is 6 degrees for the subject device and 9 degrees for the predicate device. Larger safe operational incline means it can climb steeper surface. We have shown the warning statement that the SM4226 scooter cannot be operated on the incline surface more than 6 degree in the user manual, so there are no new safety and effectiveness concerns raised for the subject device.

Scooter weight (without battery): It is 73.7 lbs. for the subject device and 92.4 lbs. for the predicate device. This difference is due to the fact that SM4226 uses lighter-weight material of aluminum alloy for the main frame of the subject device, and predicate device uses heavier-weight material of steel. There are no new safety and effectiveness concerns raised due to the smaller scooter weight of the SM4226.

Cruising range: It is 6.8 miles for the subject device and 9.32 miles for the predicate device. The difference of cruising range is mainly due to the fact that the subject device has larger loading capacity than the predicate device. There are no new safety and effectiveness concerns raised for the subject device.

Maximum loading: It is 297 lbs. for the subject device and 264 lbs. for the predicate device. Because the subject device is a larger scooter than the predicate device, the maximum loading of the subject device is larger than the predicate device. There are no new safety and effectiveness concerns raised for the subject device due to the larger maximum loading.



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Turning radius: It is 45.2” for the subject device and 64.9” for the predicate device. A smaller wheelbase can offer a tighter radius. While a larger wheelbase, such as those on large trucks, will have a larger radius. The smaller turning radius of the subject device means it is easier to make a turn than the predicate device in a tighter space. There are no new safety and effectiveness concerns raised for the subject device due to the smaller turning radius.

Maximum obstacle climbing ability: it is 1.96” for the subject device and 1.58” for the predicate device. The larger maximum obstacle climbing ability leads to climbing larger obstacle for the subject device. This difference does not raise any new safety and effectiveness concerns for the subject device.

Ground clearance: it is 1.96” for the subject device and 1.77” for the predicate device. This dimension is of more concern to the customers due to the bad road conditions. The customers prefer vehicles having higher ground clearance in the market. and this higher ground clearance can avoid more foreign impacts on the battery pack. This difference does not raise any new safety and effectiveness concerns for the subject device.

- **CONCLUSIONS**

The conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified above. Thus, the subject device is substantially equivalent to the predicate device.