



December 20, 2024

Lichtmega Technology Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, Dongfang Building, 1500# Century Ave
Shanghai, 200122
China

Re: K242628/S001
Trade/Device Name: Scooter (PS30)
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 3, 2024
Received: December 3, 2024

Dear Ivy Wang:

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

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

Indications for Use

Submission Number (if known)

K242628

Device Name

Scooter (PS30)

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)

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Prescription Use (Part 21 CFR 801 Subpart D)

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Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Scooter (PS30)
Common Name	Motorized three-wheeled vehicle
Classification Name	Vehicle, Motorized 3-Wheeled
Regulation Number	890.3800
Product Code(s)	INI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K182471	Scooter	INI

Device Description Summary

21 CFR 807.92(a)(4)

This scooter 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.

The PS30 Scooter has a base with aluminum alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, a tiller console, an electric motor, an electromagnetic brake, 1 rechargeable lithium Battery with an off-board charger. The movement of the scooter is controlled by the rider who operates the throttle lever, speed control dial 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.

The scooter is provided in four colors - cherry Red, Neptune Blue, Sunburst Orange, Frozen Grey Mat, for the outer shell of wheels and consoler panel.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed device has same indications for use to the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The design and technological characteristics of the proposed device scooter is identical to the predicate device. There are minor differences between the device is the dimension, frame material, travel distance, turning radius, ground clearance, controller, tire dimension, slope grade ability, maximum speed and loading weight. According to ISO7176 series standards and the test records support its safety and effectiveness. There is no deleterious effect on safety and effectiveness due to the minor differences do not influence the intended use of the device.

Therefore, the proposed Scooter is substantially equivalent (SE) to The Scooter (K182471).

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical tests were conducted to verify that the subject device met all design specifications and provided support of the substantial equivalence determination. The test results demonstrated that the proposed device complies with 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 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 procedures

ISO 7176-25:2013 Wheelchairs - Batteries and chargers for powered wheelchairs

Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020.

The clinical study is not applicable.

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K182471.