January 8, 2025

W'u's Tech Co., Ltd.
℅ Ke-Min Jen
Official Correspondent
Wu's Tech Co., Ltd.
No. 225, Yuan Peir St.
Hsin-Chu City, Taiwan 30093
Taiwan

Re: K240590
Trade/Device Name: Electrical Scooter, WT-T4SU
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 10, 2024
Received: December 10, 2024

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 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

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)*

K240590

Device Name

Electrical Scooter (WT-T4SU)

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.

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510(k) Summary (21 CFR 807.92)

Submitter's Name:	Wu's Tech Co., Ltd.
Date summary prepared:	December 10, 2024
Device Name:	Electrical Scooter, WT-T4SU
Classification Name	Motorized Three-Wheeled Vehicle Class II, 21 CFR 890.3800
Product Code:	INI
Company contact person:	Dr. KE-MIN JEN Email: ceirs.jen@msa.hinet.net TEL: 886-3-5208829
Predicate Device:	Manufacturer: Wu's Tech Co., Ltd. Device name: Electrical Scooter, model WT-T4QP2 510(k) number: K222729

- **Indications for Use**:

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

- **Device Description:**

WT-T4SU is for indoor or outdoor uses, and it is Lithium-ion battery powered and configured with four solid wheels, a seat, a turning tiller, and a control panel.

WT-T4SU is driven by two PU solid rear wheels (7.28" x 1.96") and steered by two PU solid castors (7.28" x 1.96"). The user can control the turning tiller to control the castors to steer the scooter's direction. Control panel has 3 functions of battery level indication, speed lever and forward/reverse selector. The user can pull the speed lever to drive forward or drive backward. Release the speed lever completely and the electromagnetic brake in the motor will be activated automatically, and the scooter will stop.

The maximum weight capacity of WT-T4SU is 264 lbs. (120 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 is 6.61 miles (10.58 km).

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.
- Ground clearance to battery over 1.4”/35 mm
- Curb climbing ability: over 1.58”/40 mm

- **Non-clinical performance tests**

  - 2-245 ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

  - 2-174 ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

  - 16-219 ANSI RESNA WC-2:2019 Section 14 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and Control Systems for Electrically Powered Wheelchairs Requirements and Test Methods

  - 16-224 ANSI RESNA WC-2 SECTION 21 American National Standard for Wheelchairs - Volume 2, Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters

  - 19-46 ANSI AAMI ES 60601-1 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

  - 19-33 IEC 62133-2:2017+ AMD1: 2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications- Part 2 Lithium systems

  - 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 electric wheelchairs,
- 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, acceleration and deceleration of electric 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 strength,
- 16-167 ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchair,
- 16-164 ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs,
- 16-25 ISO 7176-13 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- 16-27 ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- 16-233 ISO 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices- Requirements and test method

- **Comparison table**

Devices / Specifications	**Subject device**	**Predicate device**	**Comparison analysis**

Manufacturer	Wu's Tech Co., Ltd.	Wu's Tech Co., Ltd.	--
Proprietary name	Electrical Scooter	Electrical Scooter	--
Model name	wT-T4SU	WT-T4QP2	--
510(k) No.	K240590	K222729	--
Indications for use	The device is intended for medical purposes to provide the mobility to persons restricted to a sitting position.	The device is intended for medical purposes to provide the mobility to persons restricted to a sitting position.	Same
Overall dimension Length Width Height	 42.9" (1090 mm) 19.7" (500 mm) 35.8" (910 mm)	 36.2" (920 mm) 16.9" (430 mm) 35.8"(910 mm)	**Different**
Seat dimension Seat width Seat depth	 16.7"(425 mm) 14.8" (375 mm)	 13.4"(340 mm) 9.1" (230 mm)	**Different**
Motor	270 W x 24 VDC x 2 pcs	180 W x 24 VDC x 2 pcs	**Different**
Battery	T4Q-2403GA Lithium-ion battery 25.2VDC / 9.9 Ah/249.48Wh	T4Q-2403GA Lithium-ion battery 25.2 VDC/ 9.9 Ah / 249.48 Wh	Same
Battery weight	4.4 lbs. (1.98 Kg) One battery pack	4.4 lbs. (1.98 kg) One battery pack	Same
Charger model & rating	Input: 100-240 VAC, 50/60 Hz Output: 24 VDC, 2 Amp	Input: 100-240 VAC, 50/60 Hz Output: 24 VDC, 2 Amp	Same
Number of Wheels	4	4	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake System	Electromagnetic brake	Electromagnetic brake	Same
Controller	Dynamic DR50	Dynamic DR50	Same
Anti- tipper	Yes	Yes	Same
Max Speed (Forwards)	4 mph (6.4 km/h)	4 mph (6.4 km/h)	Same
Main frame material	Fixed / 6063 aluminum alloy	Fixed / 6063 aluminum alloy	Same
Use	Indoor / outdoor	Indoor/ outdoor	Same

environments			
Front wheel size & type	7.28” x 1.96” Solid x 2	6.5” x 1.96” Solid x 2	**Different**
Rear wheel size & type	7.28” x 1.96” Solid x 2	7.28” x 1.96” Solid x2	Same
Maximum safe operational incline	6 degrees	6 degrees	Same
Manual folding	No	Yes	**Different**
Scooter Weight without Battery	60.5 lbs. (27.5 kg)	41.4 lbs. (18.82 kg)	**Different**
Cruising Range	6.6 miles (10.58 km)	9.1 miles (14.5 km)	**Different**
Max Loading	264 lbs (120 kg)	250 lbs .(115 kg)	**Different**
Turning Radius	48.2” (1225 mm)	55.9” (1420 mm)	**Different**
Maximum obstacle climbing	1.58” (40 mm)	1.58” (40 mm)	Same
Ground clearance	1.4” (35 mm)	1.1” (29 mm)	**Different**

- **Substantial equivalence discussion**

  We will not discuss the items same or similar in this substantial equivalence discussion section. We will discuss the items different, i.e., Overall dimension, Seat dimension, Motor, Front wheel size, Manual folding, Scooter weight, Cruising range, Maximum loading, Turning radius, Ground clearance.

  Overall dimension: The differences between overall dimensions in width will lead to different comfort, and difference in length will lead to different sizes of scooter, thus we can tell that the subject device is a bigger-size scooter than the predicate device. There is no any new safety and effectiveness concerns raised for the subject device.

  Seat dimension: The differences between seat dimensions in width and in depth will lead to different comfort to the users, that is bigger seat dimensions will have more comfort feeling

for supporting the users' weight. Thus the subject device has more comfort feeling than the predicate device, there is no any new safety and effectiveness concerns raised for the subject device.

Motor: it is 270 W for the subject device and 180 W for the predicate device. Because the subject device is a larger-size scooter than the predicate device, it is necessary to use a motor with larger power to drive the scooter. This difference of the motor will not raise any new safety and effectiveness concerns for the subject device.

Front wheel size: Front wheel sizes, which are 7.28" x 1.96" PU solid tire type x 2 for the subject device and 6.5" x 1.96" PU solid tire type x 2 for the predicate device, are different for both devices. As seen from the data. the differences of the front wheel sizes are minor, and front wheels are used for steering scooter's direction, and the difference of front wheel size will lead to the minor difference of ground clearance, and they will not raise any new safety and effectiveness concerns for the subject device.

Manual folding: There is no manual folding function for the subject device and there is manual folding function for the predicate device. This difference will lead to less convenience of storage or transfer for the subject device, and this result will not raise any new safety and effectiveness concerns for the subject device.

Scooter weight: It is 60.5 lbs. for the subject device and 41.4 lbs. for the predicate device. Because the subject device is designed to be a larger-size scooter than the predicate device, the scooter weight of the subject device is surely heavier than the predicate device. There is no new safety and effectiveness concern raised for the subject device.

Cruising range: It is 6.6 miles for the subject device and 9.1 miles for the predicate device. The difference of cruising range is due to the use of same battery and motor and different loading or weight of the scooter. The subject device is a heavier scooter than the predicate device and uses the same battery and motor as the predicated device, so according to the conservation of work energy principle, the cruising range will be shorter than the predicate device. There are no any new safety and effectiveness concerns raised by the less cruising range of the subject device.

Maximum loading: It is 264 lbs. for the subject device and 250 lbs. for the predicate device. Because the subject device is a bigger-size scooter than the predicate device, the maximum loading of the scooter surely will be larger than the predicated device. and there are no any new safety and effectiveness concerns raised by the different maximum loading for the subject device.

Turning radius: It is 48.2" for the subject device and 55.9" for the predicate device. The less turning radius of the subject device than the predicate device will bring more space than the predicate device to make a turn, it means there is more safety for the subject device. There are no any new safety and effectiveness concerns raised by the different turning radius of the subject device.

Ground clearance: it is 1.4" for the subject devise and 1.1" for the predicate device. This

difference of the ground clearance will lead to more moving space for the subject device than the predicate device. This difference will not raise any new safety and effectiveness concerns for the subject device.

- **CONCLUSIONS**

The subject devices, WT-T4SU, are as safe and effective as, and function in a manner equivalent to the predicate device, WT-T4QP2 (K222729). The conclusions drawn from the non-clinical tests demonstrate that the devices perform as well as the legally marketed device identified in the submission.