



March 28, 2023

Wu's Tech Co., Ltd.
% Dr. Jen Ke-Min
Contact Person
Chinese European Industrial Research Society
No. 58, Fu-Chiun St
Hsin-Chu City, Taiwan 300113
Taiwan

Re: K222729

Trade/Device Name: Electrical Scooter, WT-T4QP2
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: February 17, 2023
Received: February 27, 2023

Dear Dr. Jen Ke-Min:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Indications for Use

510(k) Number (if known)
K222729

Device Name
Electric Scooter, WT-T4QP2

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) number: K222729

510(k) Summary (per 21 CFR 807.92)

Submitter's Name: ***Wu's Tech Co., Ltd.***
No.225, Yuan Peir St., Hsinchu, Taiwan ROC 30093

Date summary prepared: August 28, 2022

Proprietary Name: Electrical Scooter, model WT-T4QP2

Common or Usual Name: Electrical Scooter

Classification Name Motorized Three-Wheeled Vehicle,
Class II, 21 CFR 890.3800

Product Code: INI

Contact Person Dr. KE-MIN JEN (email: ceirs.jen@msa.hinet.net)
TEL: 886-3-5208829

Predicate Device PUC Perfect Union Co., Ltd.
Device name i3 Foldable Mobility Scooter

510(k) Number K191356

- **Indications for Use:**

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

- **Device Description:**

WT-T4QP2 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-T4QP2 is driven by two PU solid rear wheels (7.28" x 1.96") and steered by two PU solid castors (6.49" 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-T4QP2 is 250 lbs. (115 kg). Its maximum forward speed is 4 mph (6.4 km/h), and its maximum safe climbing incline angle is 6 degrees.

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 1.1"/28 mm
- ◆ Curb climbing ability over 1.58"/40 mm

● **Performance Testing:**

- ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability, 1999.
- 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 for determination of theoretical distance range,
- ISO 7176-5:2008 Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space,
- ISO 7176-6:2001 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs,
- ISO 7176-7:1998 Wheelchairs - Part 7: Determination of seating dimensions - Definitions and measuring method,
- ISO 7176-8:1998 Wheelchairs - Part 8: Static, impact and fatigue strength for manual wheelchairs,
- 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 7176-16: 2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices
- RESNA WC-2:2019 Section 14 Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- RESNA WC-2:2019 Section 21 Requirements and test method electromagnetic compatibility of powered wheelchairs and motorized scooters.

- **Biocompatibility evaluation per ISO 10993-1:2018**

Patient-contacting Parts	Materials	Rational according to Wu's Tech expertise	Tests conducted	Verdict
Handle bar grip	DIOSHY TPV	No customer claim with adverse conditions for more than 300 thousand units in the market.	Cytotoxicity, Sensitization and Irritation tests	Pass
Seat	PU	No customer claim with adverse conditions for more than 300 thousand units in the market.	Cytotoxicity, Sensitization and Irritation tests	Pass
Speed lever	PVC (NAN YA FR-PA66)	No customer claim with adverse conditions for more than 250 thousand units in the market.	Cytotoxicity, Sensitization and Irritation tests	Pass

● **Comparison table**

Devices Specifications	Subject device	Predicate device	Comparison verdict
Manufacturer	Wu's Tech Co., Ltd.	PUC Perfect Union Co., Ltd.	--
Proprietary name	Electrical Scooter	Foldable Mobility Scooter	--
Model name	WT-T4QP2	i3	--
510(k) No.	TBA	K191356	--
Indication 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
Overall Dimensions (LxWxH)	36.2" x 16.9" x 35.8"	39.9" x 18.4"x 38.6"	Similar
Manual folding	Yes	Yes	Same
Operating environments	Indoor/ outdoor	Indoor/outdoor	Same
Number of Wheels	4	4	Same
Frame	Fixed / Aluminum alloy	Fixed / Aluminum alloy	Same
Front wheel size & type	6.49"x 1.96"x2 (PU solid tire)	7" x 2"x 2 (PU Solid tire)	Similar
Rear wheel size & type	7.28"x 1.96"x2 (PU solid tire)	8" x 2"x2 (PU solid tire)	Similar
Battery	One Lithium-ion battery pack 25.2 VDC /10.35 Ah	Two Lithium-ion batteries 25.4 DCV/ 11.6 Ah	Similar

Charger type & rating	Off-board charger Input AC100-240V, Output DC 29.4V, 2A	Off-board charger Input: AC100-240V Output: DC 29.4 V	Same
Battery weight	4.4 lbs. (1.98 kg)	3.8 lbs. (1.72 kg)	Similar
Armrest	No	No	Same
Motor	DC24V / 180W	DC 24V /270W	Similar
Driving System	Rear wheel drive	Rear wheel drive	Same
Brake System	Electromagnetic brake	Electromagnetic brake	Same
Anti-tipper	Yes	Yes	Same
Max Forward Speed	4 mph /6.4 km/h	3.7 mph /6.0 km/h	Similar
Biocompatibility	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	Same
Height adjustable tiller	No	Yes	Different
Back upholstery	PU Foam	Fabric	Different
Maximum safe operational incline	6 degrees	8 degrees	Different
Weight, w/ Battery w/o Battery	45.8 lbs. (20.8 kg) 41.4 lbs.(18.82 kg)	59.5 lbs. (26.99 kg) 55.6 lbs. (25.24 kg)	Different
Cruising Range	9.06 miles/14.5 km	5.67 miles /9.13 km	Different
Max Loading	250 lbs./115 kg	300 lbs. / 137 kg	Different
Turning Radius	55.9" / 1420 mm	59" / 1500 mm	Different
Electronics controller	Dynamic DR50	Penny & Giles S-Drive	Different
Ground clearance	1.1"/ 28 mm	1.7"/ 43 mm	Different
Curb climbing	1.58"/ 40 mm	2"/50 mm	Different

- **Substantial equivalent discussion**

The same or similar items will not be discussed and only the different items will be discussed.

The height of **turning tiller** for the subject device cannot be adjusted and it can be adjusted for the predicate device. A height-adjustable turning tiller means the user can change the height of turning tiller according to the sizes of different users, thus bring more convenience to the users. A height adjustable tiller also has a risk of loose of fixing knob, and this harm will lead to serious injury of users in some cases. Though, a fixed-height tiller has no this kind of convenience, it can keep safety well. There are no any new safety or effectiveness concerns raised by the subject device due to a fixed height tiller.

The material of **back upholstery** for the subject device is PU Foam and it is Fabric for the predicate device. The PU Foam material has soft feeling to users, and fabric material has some kinds of hardness feeling to users. The safety concerns for back upholstery focus on the ignition resistance testing, and the subject device passed the *ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices*. Thus, there are no any new safety or effectiveness concerns raised by the subject device for the different back upholstery materials used.

The **Maximum safe operational incline** for the subject device is 6 degrees and it is 8 degrees for the predicate device. The difference of 2 degrees incline means the predicate device can climb steeper incline than the subject device. But we have informed the users of not to operate the subject device on the incline higher than 6 degrees in the labeling. So, there are no any new safety and effectiveness concerns raised by subject device for a 6-degree maximum safe operational incline.

The **Scooter weight with battery** is 45.8 lbs. for subject device and it is 59.5 lbs. for predicate device. The predicate device is heavier than the subject device by 13.7 lbs. The 13.7 lbs. difference mainly comes from the larger overall dimensions of frame for predicate device. Larger scooter weight will lead to a smaller cruising range according to the principle of conservation of energy. The difference between these two scooters' weight will not raise any new safety and effectiveness concerns for the subject device.

The **Cruising range** is 9.06 miles for the subject device and it is 5.67 miles for the predicate device. The difference of cruising range just comes from different designs of the scooters, not related to safety or effectiveness concerns. Moreover, we provide the 9.06 miles cruising range of WT-T4QP2 in the relevant labeling to inform the users of this cruising range. Normally, scooter with larger cruising range leads to lower frequency of charging battery, thus bring about more convenience to the user. There are no any new safety and effectiveness concerns raised by the subject device due to the larger cruising range.

The **Max loading** is 250 pounds for the subject device and it is 300 pounds for the predicate device. We provide the max loading data in the WT-T4QP2 labeling to inform users of this data. The users have the duty of noticing and observing the labeling, thus, there are no any new safety and effectiveness concerns raised by the subject device due to the different max loading.

The **Turning radius** is 55.9 inches for subject device and it is 59 inches for the predicate device. The larger turning radius will have more limitations of turning around space to the scooter with larger radius, i.e., predicate device. So, there are no any new safety and effectiveness concerns raised by the subject device.

The **Electronics controller** is Dynamic DR50 for subject device and it is PG S-Drive for predicate device. The subject device which contains the electronic controller DR50 together passes the RESNA WC-2:2019 Section 14, thus safety of electronic controller is ensured, and there are no any new safety and effectiveness concerns raised by the subject device due to using different electronic controller.

The **Ground clearance** is 1.1 inches for subject device and it is 1.7 inches for predicate device. The users should notice this data in labeling when operate the scooter to pass the obstacle, otherwise there is damage to the chassis of scooter. If the users observe the labeling, there are no any new safety and effectiveness concerns raised by the subject device due to the smaller ground clearance.

The **Curb climbing** is 1.58 inches for the subject device and it is 2 inches for predicate device. The users should notice this data in labeling when operate the scooter to meet the curb, otherwise the scooter will not pass over the curb and will have impact on the scooter. If the users observe the curb labeling, there are no any new safety and effectiveness concerns raised by the subject device due to the smaller climbing curb.

- **Conclusions:**

The subject device, WT-T4QP2, is as safe and effective as, and functions in a manner equivalent to the predicate device - i3 Foldable Mobility Scooter. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.