December 21, 2020

Wu's Tech Co., Ltd.
% Jen Ke-Min
Chinese-European Industrial Research Society
No. 58, Fu-Chiun St
Hsin-Chu City, Hsinchu 30067
Taiwan

Re: K192308
Trade/Device Name: Wu's Electrical Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: September 29, 2020
Received: October 5, 2020

Dear 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,

Heather Dean, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192308

Device Name
Wu's Electrical Scooter. WT-M4JKx

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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伍氏科技股份有限公司
WU'S TECH CO., LTD
新竹市元培街225號 統一編號/70711910
Telephone/886-3-5382105 FAX /886-3-5382191
No.225 Yuan Peir St. Hsinchu,Taiwan R.O.C.
E-MAIL:wustech@wustech.com.tw

510(k) Summary of Safety and Effectiveness

(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:	December 11, 2020
Proprietary Name:	Wu's Electrical Scooter, WT-M4JKx
Common or Usual Name:	Electrical Scooter
Classification Name	Motorized 3-Wheeled Vehicle Class II, 21 CFR 890.3800
Product Code:	INI
Contact Person:	Dr. Jen, Ke-Min Email: ceirs.jen@msa.hinet.net TEL: +886-3-5208829, FAX: +886-3-5209783
Predicate Device	Wu's Tech Co., Ltd. Wu's Electrical Scooter, WT-M4Jr K032489

- **Indications for Use**:

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

- **Device Description:**

The Wu's Electrical Scooter, WT-M4JKx, is an indoor-use electrical scooter that is battery operated. It has a base with 4 wheels, a seat and 2 armrests. The movement of the electrical scooter is controlled by the rider who uses speed control lever to control the direction and speed of an electrical scooter. The motor power is 470W. The device uses a PG S-Drive 70A electronic controller. The device is provided with an off-board battery charger (Input: AC100-240V, Output: DC 24V, 5 Amp). The maximum weight capacity of WT-M4JKx is 400 lbs (182 kg), and its maximum forward speed is 5.9 mph (9.5 km/h).

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: **1.77"**/45 mm
- Curb climbing ability: **1.96"**/50 mm

- **Compliant Testing Standards**

Safety standards:

- ✓ RESNA WC-1:2009 Wheelchairs – Volume 1 Requirements and test methods for wheelchairs (including scooter)
- ✓ RESNA WC-2:2009 Wheelchairs – Volume 2 Additional requirements for wheelchairs (including scooter) with electrical systems

EMC standard:

- ✓ RESNA WC-2:2009 Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters

Bench Testing:

- ✓ ISO 7176-16:2012 – Wheelchairs – Part 16: Resistance to ignition of postural support devices.
- ✓ ISO 7176-25: 2013 – Wheelchairs – Part 25: Batteries and Chargers for Powered Wheelchairs
- ✓ RESNA WC-1 Section 1:2009
- ✓ RESNA WC-1 Section 2:2009
- ✓ RESNA WC-1 Section 3:2009
- ✓ RESNA WC-1 Section 4:2009
- ✓ RESNA WC-1 Section 5:2009
- ✓ RESNA WC-1 Section 6:2009
- ✓ RESNA WC-1 Section 7:2009
- ✓ RESNA WC-1 Section 10:2009
- ✓ RESNA WC-1 Section 11:2009
- ✓ RESNA WC-1 Section 13:2009
- ✓ ISO 7176-15:1996
- ✓ ISO 7176-14:2008

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E-MAIL:wustech@wustech.com.tw

- **Biocompatibility evaluation of patient-contacting parts**

Patient-contacting Parts	Material's name & Color additive	Direct or Indirect contact / Contact classification & contact duration	Tests conducted	Rational for the tests conducted
1. Headrest Seatback Seat leather Safety belt	PVC Vinyl & Color additive: Diphenylmeth-ane 4	Direct-contact / Surface contacting less than 24 hours duration	Cytotoxicity Sensitization Skin Irritation tests	ISO 10993-1:2009
2. Armrest	PU Foam & Color additive: Diphenylmeth-ane 4	Direct-contact / Surface contacting less than 24 hours duration	Cytotoxicity Sensitization Skin Irritation tests	ISO 10993-1:2009
3. Horn button	Dow Corning RBB-6671-70 + RBB-6671-70 + XE20-523-5U + Colourant Techi Black 1801 & Color additive: Solvent Yellow	Direct-contact / Surface contacting less than 24 hours duration	Cytotoxicity + skin Irritation & delayed-type hypersensitivity (Epicutan test) Tests	ISO 10993-5:2009 ISO 10993-10:2013
4. Speed dial	Makrolon 6557 (PC material) & Color additive: Carbon black	Direct-contact / Surface contacting less than 24 hours duration	Cytotoxicity test	ISO 10993-5:2009
5. REM060/110 bottom case	Makroblend EL700 (PC+PET materials) & Color additive: Carbon black	Direct-contact / Surface contacting less than 24 hours duration	Cytotoxicity + Skin irritation & delayed-type hypersensitivity (Epicutan test) Tests	ISO 10993-5:2009 ISO 10993-10:2013
6. REM050/100 (Full joystick control module)	Makroblend EL 700 + Makrolon 6557 & Color addtitive: Carbon black	Direct contact / Surface contacting less than 24 hours duration	Skin irritation and delayed-type hypersensitivity Tests (Epicutan test)	ISO 10993-10:2013
7. Footrest	Polylac ABS & Color additive: Carbon black	Indirect-contact / Surface contacting less than 24 hours duration	MSDS	*Polylac ABS material is a common and mature material for wheelchair's part, and was adopted by many wheelchair manufacturers in the current market. *There are no customer claims with adverse conditions for more than thousands of units sold in the market according to our sale experience.
8. Delta handle bar	PVC Vinyl & Color additive: Polyol, Pigment	Direct-contact / Surface contacting less than 24 hours duration	Cytotoxicity Skin irritation Sensitization	ISO 10993-5:2009 ISO 10993-10:2010

9. Speed lever	ε-Caprolactam resin	Direct-contact / Surface contacting less than 24 hours duration	Cytotoxicity Skin irritation Sensitization	ISO 10993-5:2009 ISO 10993-10:2010
10. Light switch	Polyamide -6 & Color additive: Solvent 37	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise
11. Indicator switch	Phenolic & Color additive: Carbon black	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise
12. Emergency switch	Phenolic & Color additive: Solvent red 135	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise
13. Delta handle bar knob	Polylac & Color additive: Carbon black	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise
14. Seat remove lever	Polyvinyl Chloride & Color additive: Polyol ,Pigment	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise
15. Seat slide lever	ε-Caprolactam resin	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise
16. Freewheel lever	Polyvinyl chloride & Color additive: Solvent Yellow	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise
17. Charging socket cover	ε-Caprolactam resin	Direct-contact / Surface contacting less than 24 hours duration	MSDS	*Low frequency of human contact and no customer claims with adverse conditions according to previous sale experience and our expertise

- **Specifications comparison table**

Model / Specification	Predicate Device	Subject Device
Manufacturer	Wu's Tech Co., Ltd.	Same
Proprietary name, model	Wu's Electrical Scooter, WT-M4Jr	Wu's Electrical Scooter, WT-M4JKx
510(k) number	K032489	TBA
Device classification name	Motorized 3-wheeled vehicle	Motorized 3-wheeled vehicle
Classification regulations	Class II, 21 CFR 890.3800	Class II, 21 CFR 890.3800
Product code	INI	INI
Same or Similarity		
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.
Number of Wheels	4	4
Movement Control Method	Speed control lever	Speed control lever
Driving System	Direct drive rear wheel (with differential gear)	Direct drive rear wheels (with differential gear)
Brake System	Electromagnetic brake	Electromagnetic brake
Charger type	Off-board charger Input: AC 100-240 V, Output: DC 24V, 5A	Off-board charger Input AC: 100-240V, Output DC 24V, 5 Amp
Electronic Controller	PG S-Drive 70A	PG S-Drive 70A
Operating environments	Indoor use	Indoor use
Differences		
Front Wheel Size	2.5 - 4" solid tire	10.2"x3.3" solid tire
Rear Drive Wheel Size	2.5 - 4" solid tire	10.2" x 3.3" solid tire
Dimension (L×W x D inch) (L×W x D mm)	46 x 22 x 35.4 inches 1170 × 560 × 900 mm	40.6 × 23.8 × 49 inches 1210 × 580 × 1040 mm
Motor Output	350W × 24V × 1 pcs	470W x 24V x 1 pcs
Weight with Battery	94.7 lbs. /43 kg	188.1 lbs. / 85.5 kg
Cruising Range	20 miles /32 km	18 miles / 29 km
Battery type	34 Ah × 12V × 2 pcs	36 Ah × 12V × 2 pcs
Slope Grade Ability	10	6°
Max Speed Forward	4 mph (6.4 km/h)	5.9 mph (9.5 km/h)
Max Loading	250 lbs. (113.5 kg)	400 lbs. (182 kg)
Folding mechanism	No folding function	Foldable backrest and armrests

- **Specification comparison discussions**

Both devices have the same indications for use, same technological designs, same number of wheels, same speed control lever, same driving system, and same brake system,

In the below, we discuss the differences between them,

- ✓ **Wheel size:** The wheel sizes for the predicate and subject devices are different. The predicate device's tires are 2.5" x 4" solid tires and the subject device's tires are 10.2"x3.3" solid tire. The wheels of predicate device are smaller than those of the subject device. Larger wheel will give more comfort to the users, and will not raise any safety and effectiveness concerns due to the different wheel size.

- ✓ **Dimensions:** The dimensions of the two devices are different. The larger depth will give more support to the legs and will bring more comfort to user's ride, and since the subject device has passed the RESNA WC-1 and RESNA WC-2 standards with respect to safety and performance aspects, and this difference does not raise any new safety and effectiveness concerns for the subject device.

- ✓ **Weight of wheelchair**: The weight of subject device is 188.1 lbs. (85.5 kg) and it is heavier than the predicate device. This difference will make a lower ratio of the *wheelchair weight/motor power output* for the subject device. The ratio of the weight/power for the subject device is 188.1 lbs / 470 W = 0.400 lbs/W and the predicate device is 94.7 lbs/ 350 W = 0.270 lbs./W. The subject device will use one joule energy per second to push 0.400 pounds of wheelchair weight, and the predicate device will use one joule energy per second to push 0.270 pounds of wheelchair weight. That is to say, the subject device consumes more battery's electrical energy than the predicate device. There are no new safety and effectiveness concerns raised for the subject device with respect to the larger weights.

- ✓ **Motor output**: The motor output for the subject device is 470W, it is larger than 350W of the predicate device. Since the volume and weight of the subject device is larger than the predicate device, the motor output of the subject device should be designed to be larger than the predicate device. The difference will not raise any new safety and effectiveness concerns for the subject device.

- ✓ **Cruising range:** In general, the cruising range depends on the wheelchair weight, battery charging condition, motors output, and cruising surface conditions. The cruising range of the subject device is 18 miles and that of the predicate device is about 20 miles. The difference between subject device and predicate device is not large. As the user knew the cruising range of the subject device is 18 miles from the user manual, they will drive the scooter in consideration of 18 miles range, and avoid driving exceeding this cruising range for each travel. There are no new safety

and effectiveness concerns raised due to this smaller cruising range.

- ✓ **Battery type:** The battery capacity of the subject device is 36 Ah and the predicate device is 34 Ah. A larger battery capacity means this battery can drive a larger range or last for a longer time. Also, the batteries of the subject device have passed the testing of ISO 7176-25:2013. These facts demonstrate there are no any new safety and effectiveness concerns raised due to using a larger battery.

- ✓ **Slope grade ability**: The slope grade ability is 10 degrees for predicate device and 6 degrees for subject device. The relevant statement of 6 degrees for the slope grade ability is placed in the user manual. If the user operates the electrical scooter according to the instructions for use, any safety and effectiveness concerns are not raised due to the smaller slope grade ability.

- ✓ The **Max Speed Forward** for the subject device is 5.9 mph, which is larger than 4 mph of the predicate device. As we know the maximum safety speed for the motorized scooter is 6 mph, there is no safety and effectiveness concerns for the difference of maximum forward speed.

- ✓ The **maximum loading** of the subject device is 400 lbs. (182 kg) and it is 250 lbs (113.5 kg) for the predicate device. The maximum loading of the subject device is much larger than the predicate device, which will bring more comfort and safety to the users. There is no any new safety and effectiveness concerns due to the difference of the maximum loading for the subject device.

- ✓ The backrest and armrests of the subject device are foldable and the predicate device has no any folding function. These more functions bring more conveniences of storage or transportation than the predicate device. There are no any safety and effectiveness concerns raised for the subject device due to the differences of folding functions.

- **RESNA standard tests comparison table**

Specification	Predicate Device: Wu's Electrical Scooter, WT-M4Jr K032489		Subject Device: Wu's Electrical Scooter, WT-M4JKx K192308	
	Test Standard	Result	Test Standard	Result
Static stability downhill (Max.)	RESNA WC/Vol.1 Section 1:1998	NA	RESNA WC/Vol.1 Section 1:2009	26°
Static stability downhill (Min.)	RESNA WC/Vol.1 Section 1:1998	12°	RESNA WC/Vol.1 Section 1:2009	16°
Static stability uphill (Max.)	RESNA WC/Vol.1 Section 1:1998	NA	RESNA WC/Vol.1 Section 1:2009	16°
Static stability uphill (Min.)	RESNA WC/Vol.1 Section 1:1998	11°	RESNA WC/Vol.1 Section 1:2009	15°
Static stability sideways (Max.)	RESNA WC/Vol.1 Section 1:1998	9°	RESNA WC/Vol.1 Section 1:2009	9.5°
Dynamic stability downhill	RESNA WC/Vol.1 Section 2:1998	10°	RESNA WC/Vol.1 Section 2:2009	6 °
Minimum braking distance from max speed	RESNA WC/Vol.1 Section 3:1998	1.15m	RESNA WC/Vol.1 Section 3:2009	1.4m
Cruising range	RESNA WC/Vol.1 Section 4:1998	32km	RESNA WC/Vol.1 Section 4:2009	29km
Overall length	RESNA WC/Vol.1 Section 5:1998	1170mm	RESNA WC/Vol.1 Section 5:2009	1210mm
Overall width	RESNA WC/Vol.1 Section 5:1998	560mm	RESNA WC/Vol.1 Section 5:2009	580mm
Folded length	RESNA WC/Vol.1 Section 5:1998	NA	RESNA WC/Vol.1 Section 5:2009	1210mm
Folded width	RESNA WC/Vol.1 Section 5:1998	NA	RESNA WC/Vol.1 Section 5:2009	580mm
Total mass	RESNA WC/Vol.1 Section 5:1998	43kg	RESNA WC/Vol.1 Section 5:2009	85.5kg
Horizontal location of axle	RESNA WC/Vol.1 Section 5:1998	NA	RESNA WC/Vol.1 Section 5:2009	750mm
Minimum turning radius	RESNA WC/Vol.1 Section 5:1998	1100mm	RESNA WC/Vol.1 Section 5:2009	1400mm
Minimum turn-around width	RESNA WC/Vol.1 Section 5:1998	1200mm	RESNA WC/Vol.1 Section 5:2009	1600mm
Maximum speed forward	RESNA WC/Vol.1 Section 6:1998	6.4km	RESNA WC/Vol.1 Section 6:2009	9.5km
Seat plane angle (Max.)	RESNA WC/Vol.1 Section 7:1998	0°	RESNA WC/Vol.1 Section 7:2009	5°

Effective seat depth	RESNA WC/Vol.1 Section 7:1998	420mm	RESNA WC/Vol.1 Section 7:2009	430mm
Effective seat width	RESNA WC/Vol.1 Section 7:1998	430mm	RESNA WC/Vol.1 Section 7:2009	460mm
Seat surface height at front edge (Max.)	RESNA WC/Vol.1 Section 7:1998	NA	RESNA WC/Vol.1 Section 7:2009	620mm
Seat surface height at front edge (Min.)	RESNA WC/Vol.1 Section 7:1998	500mm	RESNA WC/Vol.1 Section 7:2009	570mm
Backrest angle	RESNA WC/Vol.1 Section 7:1998	10°	RESNA WC/Vol.1 Section 7:2009	10°
Backrest height	RESNA WC/Vol.1 Section 7:1998	360mm	RESNA WC/Vol.1 Section 7:2009	360mm
Obstacle climbing (Max.)	RESNA WC/Vol.1 Section 10:1998	50mm	RESNA WC/Vol.1 Section 10:2009	50mm
Obstacle climbing (Min.)	RESNA WC/Vol.1 Section 10:1998	20mm	RESNA WC/Vol.1 Section 10:2009	15mm
Footrest to seat distance (Max.)	ISO7176-15:1996	460mm	ISO7176-15:1996	475mm
Footrest to seat distance (Min.)	ISO7176-15:1996	410mm	ISO7176-15:1996	425mm
Leg to seat surface angle	ISO7176-15:1996	90°	ISO7176-15:1996	90°
Armrest to seat distance	ISO7176-15:1996	210mm	ISO7176-15:1996	210mm
Front location of armrest structure	ISO7176-15:1996	305mm	ISO7176-15:1996	320mm

- **RESNA standards test comparison discussions**

1) RESNA WC-1 Section 1

The standard used for testing the static stability of the subject device is RESNA WC-1 Section 1:2009, but the standard used for the predicate device is RESNA WC-1 Section 1:1998. The subject device used updated standard.

The testing results show that the static stability **downhill** for the subject device is 26 degrees (Max.) / 16 degrees (Min.), the static stability **uphill** is 16 degrees (Max.) / 15 degrees (Min.) and the static stability sideways is 9.5 degrees. All of the static testing results for the subject device are larger than the predicate device. The differences of the angles show that the subject device has more static stability in three ways than the predicate device. So there are no any new safety and effectiveness concerns raised for the subject device due to the static stability differences.

2) RESNA WC-1 Section 2

The standard used for testing the dynamic stability of the subject device is RESNA WC-1 Section 2:2009, but the standard used for the predicate device is RESNA WC-1 Section 2:1998. The subject device used updated standard.

The dynamic stability downhill is 6 degrees for the subject device and is 10 degrees for the predicate device. AS we knew the Americans with Disabilities Act Accessibility (ADAAG) Section 4.7.2 Slope has regulated that the angle of the slopes that may be encountered in public place and accessible environments that comply with the ADAAG will be required not to have slopes greater than 1:12 (4.8 degrees). The risk level of tip over due to the 4-degree less dynamic stability has been mitigated to an acceptable level by the slope limitation requirements of ADAAG and the disclosure of the dynamic stability information in the user manual. There are no safety and effectiveness concerns raised by the 4-degree less dynamic stability difference for the subject device.

3) RESNA WC-1 Section 3

The standard used for testing minimum braking distance of the subject device is RESNA WC-1 Section 3:2009, but the standard used for the predicate device is RESNA WC-1 Section 3:1998. The subject device used updated standard.

The minimum braking distance from maximum speed is 1.40 m for subject device and is 1.15 m for predicate device. The subject device needs more 0.25 m distance to stop the wheelchair from the maximum speed than the predicate device. As we knew, the max forward speed for the subject device is 5.9 mph, and it is 4 mph for the predicate device. The higher-speed wheelchair normally needs more braking distance to stop the wheelchair. Since the minimum braking distance information was disclosed in the user manual, the risk level of larger braking distance was reduced to an acceptable level. There are no any safety and effectiveness concerns raised for the subject device due to this braking difference of 0.25 meters.

4) RESNA WC-1 Section 4

The standard used for testing the cruising range of the subject device is RESNA WC-1 Section 4:2009, but the standard used for the predicate device is RESNA WC-1 Section 4:1998. The subject device used updated standard.

The cruising range for the subject device is 29 km and it is 32 km for the predicate device. If the user got used to the 29 km cruising range and already knew when the wheelchair needed to be charged, the user would not meet the low-battery situation, which resulted to abnormal driving situation. Thus, based on the above, there are no any new safety and effectiveness concerns raised by this shorter cruising range for the subject device.

5) RESNA WC-1 Section 5

The standard used for testing the overall dimensions of the subject device is RESNA WC-1 Section 5:2009, but the standard used for the predicate device is RESNA WC-1 Section 5:1998. The subject device used updated standard.

The overall length / width is tested to be 1210 / 580 mm for the subject device and it is 1170 / 560 mm for predicate device. These minor differences mean the subject device is bigger than the predicate device, thus not related to the safety aspects.
The total mass for the subject device is 85.5 kg and it is 43 kg for the predicate device, and the difference comes from bigger sizes of the subject device. The heavier wheelchair will lead to more comfortable feeling and less cruising range. There are no any new safety and effectiveness concerns raised by this difference for the subject device.

The minimum turning radius and minimum turn-around width are 1400 / 1600 mm for the subject device and they are 1100 / 1200 mm for the predicate device. The larger minimum turning radius and minimum turn-around width for the subject device mean that it needs considering more space to make a turn or a turn-around. Since this information was disclosed in the user manual to the users, the risk level of shortage of space was reduced to an acceptable level. There are no any new safety and effectiveness concerns raised by these differences for the subject device.

6) RESNA WC-1 Section 6

The standard used for testing the maximum forward speed of the subject device is RESNA WC-1 Section 6:2009, but the standard used for the predicate device is RESNA WC-1 Section 6:1998. The subject device used updated standard.

The forward speed for the subject device is 5.9 mph and the predicate device is 4 mph. The higher forward speed of the subject device requires more braking distance than the predicate device. The maximum forward speed information was disclosed in the user manual to the users, and the risk level of higher speed was reduced to an acceptable level. There are no any new safety and effectiveness concerns raised by the difference of higher speed for the subject device.

7) RESNA WC-1 Section 7

The standard used for testing the angle and the dimensions of the subject device is RESNA WC-1 Section 7:2009, but the standard used for the predicate device is RESNA WC-1 Section 7:1998. The subject device used updated standard.

The seat plane angle is tested to be 5 degrees for the subject device and it is 0 degree for the predicate device. This difference will result in backward inclination of the user or less happening chance of forward tip-over for the subject device and no any new safety and effectiveness concerns were raised due to the seat plane angle difference for the subject device.

The effective seat depth / effective seat width are tested to be 430 / 460 mm for the subject device and 420 / 430 mm for the predicate device. These differences can result in different comfort feeling during driving period, and they are not related to the safety aspects.

The minimum / maximum seat surface heights at front edge is 570 / 620 mm for the subject device and 500 / 500 mm for the predicate device. The seat surface height of the predicate device is fixed. It means the minimum seat height for the subject device is larger than the predicate device by 70 mm. The seat surface height of the subject device can be adjusted by 50 mm according to the comfortable feeling of users, and it is not related to the safety aspects. There are no any new safety and effectiveness concerns raised by the difference of larger seat surface height for the subject device.

8) RESNA WC-1 Section 10

The standard used for testing the climbing obstacle of the subject device is RESNA WC-1 Section 10:2009, but the standard used for the predicate device is RESNA WC-1 Section 10:1998. The subject device used updated standard.

The maximum / minimum obstacles climbing are 50 / 15 mm for the subject device and 50 / 20 mm for the predicate device. The maximum obstacles climbing are the same and the minimum obstacles are different by 5 mm. The obstacles climbing were disclosed in the user manual and the users will notice the obstacles climbing range, 50 mm to 15 mm, and they are instructed to follow the instructions for use to operate the wheelchair. Thus, there are no any new safety and effectiveness concerns raised due to the minor difference of the climbing obstacle for the subject device.

9) ISO 7176-15

The standard used for testing the relevant distances and angle of the subject device is ISO 7176-15:1996, and the standard used for the predicate device is ISO 7176-15:1996. Both devices used the same standard.
Footrest to seat distances (Max./ Min.) were tested to be 475 /425 mm for subject device and 460 / 410 mm for predicate device. These distances for both devices can be adjusted 50 mm by changing the vertical position of the footrest between the minimum position and maximum position. The users of two devices can adjust the positions of the footrest according to the comfort feeling at various positions. These differences are not related to any safety aspects. There are no any new safety and effectiveness concerns raised due to these differences for the subject device.

Front location of armrest structure is 320 mm for the subject device and is 305 mm for the predicate device. The armrest is intended for use for resting arms, and people's arms have minor differences of lengths, so the front location of armrest structure for the larger overall design of the subject device is 15 mm larger than the predicate device accordingly. It is not related to any safety aspect. There are no any new safety and effectiveness concerns raised by the difference of larger front location of armrest structure for the subject device.

- **CONCLUSIONS**

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K032489 Wu's Tech WT-M4Jr. identified in the submission. Thus, the subject device is **substantially equivalent** to the predicate device.