February 16, 2019

Wu's Tech Co., Ltd.
Dr. Jen, Ke-Min
Contact Person
No. 225, Yuan Peir St.
Hsin-Chu City, 30093 Cn

Re: K181163
Trade/Device Name: Wu's Powered Wheelchair, Mambo 30
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: November 12, 2018
Received: November 20, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K181163

Device Name
Wu's Powered Wheelchair, Mambo 30

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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5. 510(k) Summary of Safety and Effectiveness

(per 21 CFR 807.92)

510(k) number	**K181163**
Submitter's Name:	**Wu's Tech Co., Ltd.**
	No.225, Yuan Peir St., Hsinchu, Taiwan ROC 30093
Date summary prepared:	February16, 2019
Proprietary Name:	Wu's Powered Wheelchair, Mambo 30
Common or Usual Name:	Powered Wheelchair
Classification Name	Powered Wheelchair
	Class II, 21 CFR 890.3860
Product Code:	ITI
Contact Person:	Dr. JEN, KE-MIN
	Email: ceirs.jen@msa.hinet.net
	TEL: +886-3-5208829, FAX: +886-3-5209783
00Predicate Device	Wu's Tech Co., Ltd.
	Wu's Powered Wheelchair, Mambo 36
	K070655

- **Indications for Use**:

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

- **Device Description:**

a) General description

The Wu's Powered Wheelchair, Mambo 30, is an indoor-use electric wheelchair that is battery operated. It has a base with six–wheeled with a seat and armrest. The movement of the wheelchair is controlled by the rider who uses joystick, located at the right-side armrest, to control the direction and speed of the wheelchair. The device is provided with an off-board battery charger. The maximum weight capacity of Mambo 30 is 300 lbs. (136 kg), and its maximum speed is 4 mph (6.4 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: **2.34"**(60 mm)
- ◆ Curb climbing ability: **2.34"**(60 mm)

b) Principle of operation

The Wu's Powered Wheelchair, Mambo 30, is battery-operated, and the battery gives the electric energy to drive the motor. The motor will then drive the wheels to rotate and the wheelchair will thus move forward or backward. If the motor does not receive the electric energy via joystick action, the motor will stop to rotate and this gives the parking brake to the wheelchair.

c) The user population

- The product is intended for the persons restricted to a sitting positon.
- The product is not intended for visually impaired people.
- The drivers need to be mentally and physically suitable to drive the powered wheelchair.
- The fingers need to work functionally.
- The device cannot be used by children until age of 12 without parental or professional approval.

- **Performance Testing**:

- ✓ ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
- ✓ ISO 7176-2:2001 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 7176-8:2014 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 7176-11:2014 Wheelchairs – Part 11 Test dummies
- ✓ ISO 7176-13: 1989 Wheelchair – Part 13: Determination of coefficient of friction of test surfaces
- ✓ ISO 7176-15: 1996 Wheelchairs -- Part 15: Requirements for information disclosure, documentation and labelling
- ✓ ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices
- ✓ ISO 7176-21:2009 Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- ✓ ISO 7176-25:2013 Wheelchairs -- Part 25: Batteries and chargers for powered wheelchairs
- ✓ ANSI/RESNA WC-2:2009 Section 14: Power and control systems for electrically powered wheelchairs-- Requirements and test methods.
- ✓ ANSI/RESNA WC-2:2009 Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters.

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

Biocompatibility assessment of patient-contacting components was performed in conformance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Patient-contacting Parts	Material's name	Contact classification & contact duration	Tests conducted
1. Headrest Seatback Seat Safety seat belt	PVC Vinyl	**Surface contact**ing-Less than 24 hours duration	Cytotoxicity + Maximization Sensitization + Skin Irritation tests
2. Armrest	PU Foam	**Surface contact**ing-Less than 24 hours duration	Cytotoxicity + Maximization Sensitization + Skin Irritation tests
3. Horn button	Dow Corning RBB-6671 -70 + RBB-6671 -70 +	**Surface contact**ing-Less than 24 hours duration	Cytotoxicity + Irritation & delayed-type hypersensitivity (Epicutan test) Tests

	XE20-523-5U + Colourant Techi Black 1801		
4. Speed dial	Makrolon 6557 (PC material)	**Surface contact**ing- Less than 24 hours duration	Cytotoxicity test
5. REM060/110 bottom case	Makroblend EL700 (PC+PET materials)	**Surface contact**ing- Less than 24 hours duration	Cytotoxicity + Irritation & delayed-type hypersensitivity (Epicutan test) Tests
6. REM050/100 (Full joystick control module)	Makroblend EL 700 + Makrolon 6557	**Surface contact**ing- Less than 24 hours duration	Irritation and delayed-type hypersensitivity Tests (Epicutan test)

- **Comparison table**

Model / Specification	Predicate Device	Subject Device
Manufacturer	Wu's Tech Co., Ltd.	Same
Proprietary name, model	Wu's Powered Wheelchair, MAMBO 36	Wu's Powered Wheelchair, MAMBO 30
510(k) number	K070655	TBA
Device classification name	Powered Wheelchair	Same
Classification regulations	Class II, 21 CFR 890.3860	Same
Product code	ITI	Same
Similarities		
Indications for use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same indications for use
Number of wheels	6	Same number of wheels
Front wheel size	5.05x1.95 inches /solid tires	Same front wheel size /solid tires
Drive wheel size	10x3.12 inches /solid tires	Same drive wheel size / solid tires
Rear wheel size	5.05x1.95 inches/solid tires	Same rear wheel size / solid tires
Movement control method	By Joystick control	Same Joystick control
Motors output &type	320W × 24V × 2 pcs	Same motors output & type
Driving system	Middle wheel direct drive	Same middle wheel direct drive
Brake system	Electromagnetic brake	Same Electromagnetic brake
Max speed forward	4 mph / 6.4 km/h	Same forward speed
Max loading weight	300 lbs. /136 kg	Same maximum loading weight
Differences		
Dimension (LxW x D inch) (LxW x D mm)	43.9 × 24.4 × 43.3 inches 1115 × 620 × 1100 mm	40.6 × 23.8 × 49 inches 1030 × 605 × 1245 mm

Weight with batteries	226 lbs. /103 kg	172.7 lbs. / 78.5 kg
Cruising range	12.5-18.7 miles /20~30 km	12.8 miles / 20.5 km
Battery type	30Ah × 12V × 2 pcs	Kung Long U1-36NE, 36Ah × 12V × 2 pcs *Complying with ISO 7176-25:2013*
Charger Type Brand & Model Rating	Off-board charger HP8204B Input: AC115/230V, Output: DC 24V, 3A	Off-board charger CTE 4C24050A Input AC 100-240V, Output DC 24V, 5 Amp *Complying with ISO 7176-25:2013*
Electronic controller	PG VR-2 60A	DYNAMIC LINX 40A *Complying with ANSI/RESNA WC-2:2009 Section 14*
Slope grade ability	8°	6°
Operating environments	Indoor/outdoor uses	Indoor use

- **Substantial equivalence discussion**

Both devices have the same indications for use, same technological designs, same number of wheels, same joystick control method, same motor output, same driving system, same brake system, same forward maximum speed, and same maximum loading.

In the below, we discuss the differences between them,

✓ **Dimensions:** The dimensions of the two devices are similar in Length and Width, but the Depth of the subject device is 5.7 inches (145 mm) larger than the predicate device. The larger depth will give more support to the legs and will bring more comfort to user's ride, and this difference does not raise any new safety and effectiveness concerns for the subject device, since the subject device has passed the ISO 7176 series standards with respect to safety and performance aspects.

✓ **Weight of wheelchair**: The weight of subject device is 54 lbs. (25 kg) smaller 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 172 lbs / 320 W = 0.5375 lbs/W and the predicate device is 0.7063 lbs/W (=226/320). The subject device will use one joule energy per second to push 0.5375 pounds of wheelchair weight, and the predicate device will use one joule energy per second to push 0.7063 pounds of wheelchair weight. That is to say, the subject device consumes less 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 smaller weights.

- ✓ **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 12.8 miles and that of the predicate device is about 12.5-18.7 miles. The difference between subject device and predicate device is not large. As the user knew the cruising range of the subject device is 12.8 miles from the user manual, they will drive the wheelchair in consideration of 12.8 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 30 Ah. A larger battery capacity means this battery can drive a larger range or last for a longer time than a smaller battery capacity under the same usage. 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 capacity.

- ✓ **Charger type**: They are the same type of off-board chargers and possess the same input and output voltages, but they are not the same brand and not from the same supplier. But the charger of the subject device has passed the ISO 7176-25:2013, it means the safety and effectiveness aspects of our charger are ensured with respect to the different brand of battery charger.

- ✓ **Electronic controller**: The suppliers and types of the electronic controller are different. But the electronic controller of the subject device has passed the *ANSI/RESNA WC-2:2009 Section 14: Power and control systems for electrically powered wheelchairs-- Requirements and test methods*, any new safety and effectiveness concerns are not raised due to using a different brand of a controller.

- ✓ **Slope grade ability**: The slope grade ability is 8 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 powered wheelchair according to the instructions for use, any safety and effectiveness concerns are not raised due to a smaller slope grade ability.

- ✓ **Operating environments:** The operating environment for the predicate device is indoor/outdoor uses and it is indoor use for the subject device. The relevant safety statements for riding indoors are placed in the device label and the user manual. The user is instructed to observe the safety statements and follow the instructions

for use. There will be no any new safety and effectiveness concerns raised with respect to its intended use of operating environments.

- **CONCLUSIONS**

The subject device, Mambo 30, is as safe and effective as, and functions in a manner equivalent to the predicate device, Mambo 36. 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.**