January 11, 2022

PUC Perfect Union Co., LTD.
Anita Chen
Advisor
8F-4, No.20, Lane 609, Sec. 5, Chungshin Road
Sanchung District
New Taipei City, 241 Taiwan

Re: K191356
Trade/Device Name: i3 Foldable Mobility Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: December 13, 2021
Received: December 16, 2021

Dear Anita Chen:

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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K191356

Device Name
i3 Foldable Mobility Scooter

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

The 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of 21 CFR Part 807.92

1. Submitter's Information

Submitter Name: PUC Perfect Union CO., Ltd.
The assigned 510(k) Number: K191356
Establishment Registration NO.: 3013603265
Address: 8F-4, No.20, Ln.609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City, Taiwan. Zip Code: 24159
TEL: +886 2 9993690
Contact Person: Anita Chen
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2. Subject Device Information

Trade Name	i3 Foldable Mobility Scooter
Common Name	Mobility Scooter
Classification Name	Vehicle, Motorized 3-Wheeled
Review Panel	Physical Medicine
Product Code	INI
Regulation Class	2
Regulation Number	21 CFR 890.3800

3. Predicate Device Information

K150987, Heartway Medical Products CO., LTD.

Trade Name	Brio S19 Powered Mobility Scooter
Common Name	Mobility Scooter
Classification Name	Vehicle, Motorized 3-Wheeled
Review Panel	Physical Medicine
Product Code	INI
Regulation Class	2
Regulation Number	21 CFR 890.3800

4. Indication for Use

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

5. Device Description

The device “i3” is an indoor/outdoor use mobility scooter that is intended to be used by a person who is able to walk but still with “minor mobility problems.” The mobility scooter “i3” is composed of metal alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a speed control throttle lever for high/low speed adjustment, a upper control console with a battery indicator, a horn, a key, and a speed control dial, a Li-ion battery with an off-board charger, a motor/electromagnetic brake assembly, an electric motor controller, and a seat/backrest set. The overall dimension of the scooter is L1014*W468*H981 mm. The total weight of the scooter is 25 kg without battery inside. It can easily be folded and unfolded for transportation in a car boot. The maximum weight capacity of “i3” is 300 lbs. (Approx.136 kg), and its maximum speed is allowed 4 mph (Approx. 6 km/h).

The speed limits while in slow is 1 mph, and is between 2~3 mph in normal. The highest curb clearance is 43 mm. The maximum safe speed to prevent tip over during operation is 3 km/hr. The minimum turning radius to prevent tip over during operation is 1500 mm.

The information on the time to brake for each noted stopping distance is given on page 3 of the ISO 7176-3 test report as found in 004 Appendix B of this submission. Other performance standards such as ANSI/RESNA WC-2: 2009 (Section 21) & (Section 14) are applicable to the device subject of the submission. The braking system in the i3 foldable mobility scooter is electromagnetic brake. It will engage automatically as soon as the patient releases the speed lever. If the electrical brake fails, the motor will struggle to turn. This situation causes the motor to struggle and draw more current from the batteries. Then, the power indicator will travel faster from right to left. Meanwhile, the PG S45 controller will detect a fault in the scooter’s electrical brakes, and then the scooter will stop by itself instantly.

The maximum distance of travel on the fully charged battery is approximately 9.13 km on a single battery while carrying the maximum weight 300lbs. However, the maximum distance of travel does vary with the condition of battery, loading capability as well as road condition. The device can be operated under safer surfaces, such as riding on smooth and uneven surfaces.

There are no accessories for the i3 Foldable Mobility Scooter.

The device has a small USB port underneath the dashboard. It is safe for a patient to charge the patient/user's cell phone using the standard USB Type-A female port with a connecting cable because the maximum amperage and voltage are less than or equal to 0.5A/5V.

A USB charging port:

- Standard USB Type-A Female port.
- Provide 5V/0.5A, however, voltage may drop more depends on battery capacity.
- Caution: the USB port is design for cell phone charging only. Do not use the port for another appliance.

- **The following surfaces are recommended not to operate on:**

- Sand land
- Wet or icy road
- Manhole cover
- Additional person riding or hanging onto the scooter
- Terrain
- Never take escalator. Only take the elevator to go up and down stairs
- Steep incline over 8 degrees
- Connect to a wrong battery charger
- Do not fold/unfold the product as accordantly
- Use a cell phone, walkie, laptop, or other radio transmitter while operating the scooter
- Turning corner at high speed

- Drive the scooter under the influence of alcohol, drugs, or medication that may affect the physical or cognitive abilities
- Power off the product when it is moving
- Hanging bags or other belonging over the steering throttle
- Carry passengers or items exceed the maximum carrying weight
- Neglect of the manufacturer's recommendation
- Exceed the maximum safe gradient

Performance Testing

The device *"i3"* is designed to fulfill the requirements of the following safety and performance standards.

1.	ISO 7176-13 First edition 1989-08-01 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
2.	ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
3.	ISO 7176-4 Third edition 2008-10-01 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
4.	ISO 7176-5 Second edition 2008-06-01 Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space
5.	ISO 7176-10 Second edition 2008-11-01 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
6.	ISO 7176-14 Second edition 2008-02-15 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods

7.	ISO 7176-21 Second edition 2009-04-01 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
8.	ISO 7176-9 Third edition 2009-11-15 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
9.	ISO 7176-11 Second edition 2012-12-01 Wheelchairs - Part 11: Test dummies
10	ISO 7176-16 Second edition 2012-12-01 Wheelchairs - Part 16: Resistance to ignition of postural support devices
11	ISO 7176-3 Third edition 2012-12-15 Wheelchairs - Part 3: Determination of effectiveness of brakes
12	ISO 7176-1 Third edition 2014-10-01 Wheelchairs - Part 1: Determination of static stability
13	ISO 7176-7 First Edition 1998-05-15 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
14	ISO 7176-8 Second editon 2014-12-15 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
15	ISO 7176-2 Third edition 2017-10 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs
16	ISO 7176-6 Third edition 2018-06 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
17	ISO 7176 - 30 First edition 2018-12 Wheelchairs --Part 30: Wheelchairs for changing occupant posture --Test methods and requirements
18	ANSI RESNA WC-1:2019 Section 1 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1: Determination of static stability
19	ANSI RESNA WC-2:2019 Section 2 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs
20	ANSI RESNA WC-1:2019 Section 3 American National Standard for Wheelchairs - Volume 1: Additional Requirements for Wheelchairs (including Scooters) Section 3: Determination of effectiveness of brakes

21	ANSI RESNA WC-2:2019 Section 4 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range
22	ANSI RESNA WC-1:2019 Section 5 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space
23	ANSI RESNA WC-2:2019 Section 6 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed of electrically powered wheelchairs.
24	ANSI RESNA WC-1:2019 Section 7 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of measurement of seating and wheel dimensions
25	ANSI RESNA WC-1:2019 Section 8 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, Iipact and fatigue strengths
26	ANSI RESNA WC-2:2019 Section 9 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for Electrically powered wheelchairs
27	ANSI RESNA WC-2:2019 Section 10 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
28	ANSI RESNA WC-1:2019 Section 11 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test mannequins
29	ANSI RESNA WC-1:2019 Section 13 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of Coefficient of Friction of Test Surfaces
30	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
31	ANSI RESNA WC-1:2019 Section 15 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for Information Disclosure, Documentation and Labeling
32	ANSI RESNA WC-1:2019 Section 16 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 16: Resistance to Ignition of Upholstered Parts - Requirements and Test Methods
33	ANSI RESNA WC-1:2019 Section 22 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheels chairs (including Scooters) Section 22: Set-up Procedures
34	ANSI RESNA WC-2:2019 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
35	IEC 60335-2-29: Safety of household and similar electrical appliance
36	IEC 62133: Secondary Cells and Batteries Containing Alkaline or other Non-Acid Electrolytes – Safety Requirements for Portable Sealed Secondary Cells and for Batteries Made From Them for Use in Portable Applications
37	IEC 60601–1–6 and IEC 62366: Medical Electrical Equipment Usability Report
38	ANSI/RESNA WC-2: 2009 (Section 21) Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods
39	ANSI/RESNA WC-2: 2009 (Section 14) Power and control system for electrically powered wheelchairs and scooters – requirements and test methods
40	ISO 10993 –10 Skin Sensitization (Maximization)
41	ISO 10993 –5 Vitro Cytotoxicity
42	ISO 10993 –10 Irritation and Skin Sensitization

6. Comparison

Item	Subject Device	Predicate Device (K150987)	Substantial Equivalent Results
Manufacturer	PUC	Heartway	-
Model No.	i3	BRIO S19	-
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
Electronics controller	Penny & Giles S-Drive	Penny & Giles S-Drive	Same
Armrest	No armrest	No armrest	Same
Height adjustable tiller	Yes	Yes	Same
Back upholstery	Fabric	Fabric	Same
Wheel Lock	Push-to-lock	Push-to-lock	Same
Frame	Fixed/Aluminum alloy	Fixed/Aluminum alloy	Same
Brake	Electromagnetic	Electromagnetic	Same
Anti-tipper	Yes	Yes	Same
Driving system	Rear wheel drive	Rear wheel drive	Same
Rear wheel	8”X2” solidX2	8”X2” solidX2	Same
Manual folding only	Yes	Yes	Same
Operating Environments	Indoor/outdoor	Indoor/outdoor	Same
Overall dimension **Overall Length** **Overall Width** **Overall Height**	L1014mm / 39.9” W468mm /18.4” H981 mm /38.6”	930 mm / 36.6” 485 mm / 19.0” 945 mm / 37.2”	Larger Dimension
Seat dimension **Seat Width** **Seat Height**	W400mm /15.7” H355 mm /13.98”	395 mm / 15.5” 350 mm / 13.75”	Same
Weight	w/batteries 26.99kgs /59.5 lbs	w/batteries 31.3kgs /69 lbs	Minor different

	w/o batteries 25.24kgs / 55.6 lbs	w/o batteries 24.0kgs / 53 lbs	
Battery weight	1.72 kg for one	3 kg	Minor different
USB charging port	Yes	No	different
Ground clearance	43 mm / 1.7”	60 mm / 2.3”	Minor different, more safety.
Front caster	7”x1.75” solid X2	7”x1.6” solid X2	Minor different
Turning Radius	1500mm/59”	820mm/32.2”	Minor different for stable design.
Incline Safe Climbing Angle	8 Degree	6 Degree	Minor different for Larger safe climbing Angle
Range per full charging	9.13 km / 5.67miles (for one battery	18 km / 11.25 miles	Minor different
Maximum speed	6 km/hr (3.7 mile/h)	8.0 km/hr (5mile/h)	Minor different
Motor	24V, 270W	3A 24V, 270W@1	same
Kerb climbing	50 mm/2”	45 mm/1.7”	Minor different
Battery charger Voltage output Model	External (off-board) charger DC29.4V (UL E491233 CE) IN2902000	External (off-board) charger 24VDC (UL E201162) 4C24050A	Minor different
Maximum Capability	137 kg / 300lbs	100 kg / 220lbs	different
Battery	Two Li – Battery 25.2V/11.6AH	Two 12Ah /12VDC	Minor different

Biocompatibility	ISO10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	same

Despite of the above differences, the two devices all completed the performance tests in accordance with ISO 7176 series standards and the ANSI / RESNA WC 2, Section 21 for the EMC test. There are no safety and effectiveness aspects concerned. Thus, the two devices are substantially equivalent.

7. Conclusion

Based on the similarities and differences discussions above, the subject device is as safe and effective as the predicate device because the subject device is a lot like the predicate device which has already been reviewed and cleared by FDA. Besides, the comparison of different characteristics with the predicate device demonstrates that the subject device is as safe and effective because the results of these tests do not affect the safety and effectiveness after verified by related performance tests. Since both devices were tested using the same FDA Recognized Consensus Standards, PUC believes that the data generated from the Heartway supports the findings of substantial equivalence. Thus, the subject device is substantially equivalent to the predicate device (K150987).

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.