June 24, 2019

Yongkang Dingchang Industry & Trade Co., LTD.
% Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.,
Fangshan District
Beijing, 102401 CN

Re: K182411
Trade/Device Name: Scooter, Model: R-100
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: May 23, 2019
Received: May 28, 2019

Dear Ray Wang:

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,

Vivek Pinto, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182411

Device Name
Scooter, Model: R-100

Indications for Use *(Describe)*
It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182411

1. Date of Preparation

   06/20/2019

2. Sponsor

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Scooter
Common Name: vehicle, motorized 3-wheeled
Model(s): R-100

Regulatory Information:
Classification Name: vehicle, motorized 3-wheeled
Classification: 2;
Product Code: INI;
Regulation Number: 21 CFR 890.3800；
Review Panel: Physical Medicine;

Intended Use Statement:
It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

5. Device Description

The Scooter (Models: R-100) is an indoor/outdoor electric scooter that is intended to be used by individuals that are able to walk, but suffer from mobility limitations. It has a base with aluminum alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, an adjustable steering column, a control panel, an electric motor, an electromagnetic brake, a rechargeable battery with an off-board charger. The movement of the scooter is controlled by the rider who operates the direction control lever, speed control switch and handle on the control panel. The device is installed with an electromagnetic brake that will engage automatically when the scooter is not in use and the brake cannot be used manually.

6. Identification of Predicate Device

Predicate #
510(k) Number: K172440
Product Name: Solax Electric Scooter
Manufacturer: Dongguan Prestige Sporting Goods Co., Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods.
ISO 7176-1:2014 Wheelchairs – Part 1: Determination of static stability.
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 and scooters for determination of theoretical distance range
ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space.
ISO 7176-6:2018 Wheelchairs – Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions.
ISO 7176-8:2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths.
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 7176-11:2012 Wheelchairs – Part 11: Test dummies.
ISO 7176-13:1989 Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces
ISO 7176-14:2008 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters – Requirements and test method.
ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices.
ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22:2014 Wheelchairs – Part 22: Set-up procedures
ISO 7176-25:2013 Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs
ISO 10993-5: 2009, Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin

sensitization.

8. Clinical Test Conclusion

No Clinical Test conducted.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device	Remark
Product Code	INI	INI	SE
Regulation No.	21 CFR 890.3800	21 CFR 890.3800	SE
Class	2	2	SE
Intended Use	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	SE
Operation Environment	For Indoor/Outdoor use	For Indoor/Outdoor use	SE

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Overall Dimensions	1022 x 537 x	930 x 450 x 865 mm	Analysis
Tires	2 x 8 inches for front wheel (solid wheel) 3 x 9 inches for rear wheel (solid wheel)	6 inches for front wheel (solid wheel) 7 inches for rear wheel (solid wheel)	Analysis
Speed	6.4 km/h (4 mph)	6 km/h (3.7 mph)	SE
Safe Gradient/Maximum Gradient	0-6°	0-12°	Analysis
Range	20.25 km (12.6 miles)	15 km (9.32 mile)	Analysis
Turning Circle	1.16 m	1.55 m	Analysis
Base weight (not including battery)	39.2 kg	24 kg	Analysis
Battery Weight	13.4 kg	1.84 kg	Analysis
Brake	Electromagnetic	Electromagnetic	SE
Drive System	Rear wheel drive	Rear wheel drive	SE
Maximum Capacity	147 kg approx	125 kg Approx.	Analysis
Ground Clearance	76.2 mm	36 mm	Analysis
Obstacle Climbing Ability	65 mm	38 mm	Analysis
Battery	Battery, 24V/20AH	Lithium battery 24 V/10AH	Analysis
Motor	24 V 200W	24V 120W	Analysis
Battery Charger	DC 24V/2A	DC 24V/2A	SE

Difference Analysis:

The design and technological characteristics of the subject device is basically similar to the predicate

device chosen. There are minor differences between the devices including overall dimensions, Tires, speed, Safe Gradient, range, Turning circle, basic weight, battery weight, Maximum capacity, Ground clearance, Battery and motor. There is no deleterious effect on safety and effectiveness due to the differences, and these minor differences do not influence the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness. Therefore, the subject device is substantially equivalent to the Solax Electric Scooter (K172440).

Table 3 Safety Comparison

ITEM	Proposed Device	Predicate Device	Remark
Performance Test	Comply with EN 12184 and ISO 7176 series	Comply with ISO 7176 series	SE
EMC	Comply with IEC 60601-1-2 and ISO 7176-21	Comply with ISO 7176-21	SE
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.