July 10, 2019

Tianjin Kepler Vehicle Industry 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: K182471
Trade/Device Name: Scooter KPL001
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 9, 2019
Received: April 11, 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
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)*
K182471

Device Name
Scooter, Model: KPL001

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.

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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: K182471

1. Date of Preparation

   07/10/2019

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): KPL001

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: KPL001) 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 metal alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, an adjustable steering column, a tiller console, an electric motor, an electromagnetic brake, rechargeable lead-acid battery with an off-board charger. The movement of the scooter is controlled by the rider who operates the throttle lever, speed control dial and handle on the tiller console. 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.

The parts of Scooter, such as seat, rear, basket, battery pack, batteries cover, could be disassembled easily. No tools will need in installation or uninstallation.

The Scooter could be detached as following steps:

a. Before operating, the knob is in the horizontal direction, then Push the lock konb forward and point to the key hole ,turn it 90 degree clockwise, the tiller will be locked in a straight ahead position.
b. Separating the seat from the scooter by lifting up the seat. If the seat is blocked while you are removing it, please loosen the seat while lifting it and turn the seat back.
c. Separating the batteries from the scooter by lifting up the battery pack.

And, the scooter could be installed as following steps:

a. Firstly, use the quick release handle to lift the frame.
b. Then, put the motor support forward, the frame hook is correctly attached to the tube.
c. Turn the tiller to a high position and tighten the tiller button.
d. The re installation of the batteries.
e. Reinstalling the seat, and turning it until it is fixed in right place.
f. The counterclockwise rotation of a knob, unlock the tiller.

6. Identification of Predicate Device

Predicate #1
510(k) Number: K172440
Product Name: Solax Electric Scooter
Manufacturer: Dongguan Prestige Sporting Goods Co., Ltd.

Predicate #2
510(k) Number: K162952
Product Name: C.T.M. Mobility Scooter
Manufacturer: Chien Ti Enterprise 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:

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 and scooters for determination of theoretical distance range
ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space.
ISO 7176-6:2001 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 K182471	Predicate Device #1 K172440	Predicate Device #2 K162952	Remark
Product Code	INI	INI	INI	SE
Regulation No.	21 CFR 890.3800	21 CFR 890.3800	21 CFR 890.3800	SE
Class	2	2	2	SE
Indication For 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.	The C.T.M. Mobility Scooter HS-328 in an indoor/outdoor scooter that provides transportation for a disabled or elderly person.	SE
Operation Environment	For Indoor/Outdoor use	For Indoor/Outdoor use	For Indoor/Outdoor use	SE

Table 2 Performance Comparison

ITEM	Proposed Device K182471	Predicate Device #1 K172440	Predicate Device #2 K162952	Remark
Overall Dimensions	1030mm/40.6” x 630mm/24.8” x 920mm/36.2”	930mm/36.6” x 450mm/17.7” x 865mm/34.1”	1120mm/44” x 590mm/23.2” x 935mm/36.8”	Analysis
Tires	7” (190 x 54 mm) for front wheel (solid wheel) 8” (215 x 70 mm) for rear wheel (solid wheel)	6 inches (160 x 45 mm) for front wheel (solid wheel) 7 inches (190 x 70 mm) for rear wheel (solid wheel)	Front wheels: 225mm/9” Rear wheels: 225mm/9”	Analysis
Speed	6.6 km/h	6 kmh/3.7 mph	8 kmh/ 5 mph	Analysis
Safe Gradient/Maximum Gradient	0-12°	0-12°	8°	SE
Range	15 km/9.32 Miles	15 km / 9.32 Miles	17.5 kg / 10.9 Miles	SE
Turning Circle	1.3 m/51.2”	1.55 m/61”	1.45m/57.1”	Analysis

Base weight (not including battery)	50 kg/110 lbs	24 kg/ 53 lbs	55kg/121.3 lbs	Analysis
Battery Weight	10.2 kg/22.5 lbs	1.84 kg/4.1 lbs	15.5 kg/34.2 lbs	Analysis
Brake	Electromagnetic	Electromagnetic	Electromagnetic	SE
Drive System	Rear wheel drive	Rear wheel drive	Rear wheel drive	SE
Brake Distance-Normal operation (Horizontal-Forward-Max speed)	1m/39.4”	No available data	1.3m/51.2”	Analysis
Time to brake	< 1 s	No available data	No available data	Analysis
Operating surface &environment	Indoor use and restricted outdoor use on pavements or paved footpaths only.	Indoor and outdoor use	Indoor and outdoor use	SE
Frame material	Carbon steel	No available data	No available data	Analysis
Frame style	Foldable seat, removable battery pack， disassemble for transport	adjustable steering column, removable battery pack, fold for transport	Disassemble for transport	SE
Frame tube size	Ø25.4	No available data	No available data	Analysis
Obstacle Climbing Ability	50 mm/1.97”	38 mm/1.5”	52 mm/2”	Analysis
Maximum Capacity	120 kg/265 lbs approx	125 kg/276 lbs Approx.	136 kg/300 lbs	Analysis
Ground Clearance	45 mm/1.8”	36 mm/1.4”	40mm/1.6”	Analysis
Battery	lead-acid 24V/12AH	Lithium battery 24 V/10AH	Lead-Acid 12V/22Ah x 2	Analysis
Motor	24 V 180W	24V 120W	No available data	Analysis
Battery Charger	DC 24V/2A	DC 24V/2A	DC 24V/5A	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, tire size, speed, Turning circle, basic weight, battery weight, Brake distance, time to brake, obstacle climbing ability, 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) and C.T.M. Mobility Scooter (K162952).

Table 3Safety Comparison

ITEM	Proposed Device K182471	Predicate Device #1 K172440	Predicate Device #2 K162952	Remark
Performance Test	Comply with ISO 7176 series	Comply with 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	Comply with ISO 7176-21	SE
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

Table 4 Test results of ISO 7176 series comparison

ITEM	Proposed Device K182471	Predicate Device #1 K172440	Predicate Device #2 K162952	Remark
ISO 7176-1	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet it's design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet it's design specification.	The Static stability has been determined after the testing according to the ISO 7176-1, and test results meet it's design specification.	SE
ISO 7176-2	The dynamic stability has been determined after the	The dynamic stability has been determined after the	The dynamic stability has been determined after the	SE

	testing according to the ISO 7176-2, and test results meet it's design specification.	testing according to the ISO 7176-2, and test results meet it's design specification.	testing according to the ISO 7176-2, and test results meet it's design specification.	
ISO 7176-3	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet it's design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet it's design specification.	The effectiveness of brakes has been determined after the testing according to the ISO 7176-3, and test results meet it's design specification.	SE
ISO 7176-4	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet it's design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet it's design specification.	The theoretical distance range has been determined after the testing according to the ISO 7176-4, and test results meet it's design specification.	SE
ISO 7176-5	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	The dimensions, mass has been determined after the testing according to the ISO 7176-5,	SE
ISO 7176-6	The maximum speed, acceleration and deceleration of scooter has been determined after the testing according to the ISO 7176-6,	The maximum speed, acceleration and deceleration of scooter has been determined after the testing according to the ISO 7176-6,	The maximum speed, acceleration and deceleration of scooter has been determined after the testing according to the ISO 7176-6,	SE
ISO 7176-7	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	The seating and wheel dimensions has been determined after the testing according to the ISO 7176-7,	SE
ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	All test results meet the requirements in Clause 4 of ISO 7176-8	SE
ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	The test results shown that the device under tests could continue to function according to manufacturer's specification after being subjected to each of the tests specified in Clause 8 of ISO 7176-9	SE
ISO 7176-10	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	The obstacle-climbing ability of device has been determined after the testing according to the ISO 7176-10,	SE
ISO 7176-11	The test dummies used in the testing of ISO 7176	The test dummies used in the testing of ISO 7176	The test dummies used in the testing of ISO 7176	SE

	series are meet the requirements of ISO 7176-11	series are meet the requirements of ISO 7176-11	series are meet the requirements of ISO 7176-11	
ISO 7176-13	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	The coefficient of friction of test surfaces has been determined, which could be used in other 7176 series tests involved	SE
ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	All test results meet the requirements in Clause 7, 8, 9, 10, 11, 12, 13, 14, 15, 17 of ISO 7176-14	SE
ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	The test results shown that information disclosure, documentation and labelling of device meet the requirements of ISO 7176-15	SE
ISO 7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	The performance of resistance to ignition meet the requirements of ISO 7176-16	SE
ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	The EMC performance results meet the requirements of ISO 7176-21	SE
ISO 7176-22	All performed tests are set up as requirements of ISO 7176-22	All performed tests are set up as requirements of ISO 7176-22	All performed tests are set up as requirements of ISO 7176-22	SE
ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	The performance of batteries and charger of device meet the Requirements in Clause 5 and 6 of ISO 7176-25	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.