December 14, 2018

Chien Ti Enterprise Co., Ltd.
Vivian Lo
Sales Manager
No. 13, Lane 227, Fu Ying Rd
New Taipei City, Hsin Chuang District, CN 24258 Taiwan

Re: K181344
Trade/Device Name: C.T.M Mobility Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: September 14, 2018
Received: September 17, 2018

Dear Vivian Lo:

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)*
K181344

Device Name
C.T.M. Mobility Scooter

Indications for Use *(Describe)*
The C.T.M. Mobility Scooter HS-115 in an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

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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*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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## 510(k) Summary

Company Name: CHIEN TI ENTERPRISE CO., LTD.
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Telephone: +886-2-29032987
Fax: +886-2-29038807
Contact Person: Ms. Vivian Lo
Summary Preparation Date: December 13, 2018

**Device Name:**
Trade Name: C.T.M. Mobility Scooter, HS-115
Classification Name: Motorized three-wheeled vehicle
Regulation Number: 890.3800
Product Code: INI
Device Class: Class 2
Panel: Physical Medicine

**PREDICATE DEVICE:**
K151944, Freerider Corporation Luggie Super

**Indications for Use (IFU) statement:**
The C.T.M. Mobility Scooter HS-115 in an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

**Device Description**
The C.T.M. Mobility Scooter HS-115 is an indoor/outdoor scooter that is powered by two 12Ah lead-acid batteries, equipped with three wheels, capacity of 115 kilograms and a lightweight adjustable seat. It's a rear wheel drive scooter with theoretical driving ranges of 10 kilometer. The movement of the scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an off-board battery charger. The maximum speed is 4 m.p.h.

**Substantial Equivalence Comparison**
The C.T.M. Mobility Scooter, HS-115 and the Freerider Corporation mobility scooter Luggie Super (K151944) have same intended use and classification name/ product code.

The C.T.M. Mobility Scooter, HS-115 and the Freerider Corporation mobility scooter Luggie Super similar design features. Regarding the HS-115, the dimensions is bigger and heavier, but not significantly. Both scooters have same 3 wheels, rear-wheel drive technology, Electro-Mechanical brakes, Dismantle for transport. The control systems are used for exact same model, Dynamic Rhino 50 controllers (DR50). The features on the tiller and controller are same. Each scooter has a single motor and two batteries. The differences are motor size, capacity and output of battery. All the differences don't affect the safety and performance after verified by safety and performance test.

The HS-115 with its built in modern technologies for improvements in effectiveness and safety, in many comparable criterions, considered fairly similar to its predicate device: Luggie Super. Furthermore, the HS-115 has been also tested to applicable ANSI/RESNA, ISO, IEC standards which are included in this submission.

| **Category** | **C.T.M. Mobility Scooter, HS-115**<br>**New device** | **Freerider Corporation Scooter Luggie Super**<br>K151944 | **Result of Comparison** |
|---|---|---|---|
| **Indications for Use (IFU) statement** | The C.T.M. Mobility Scooter HS-115 in an indoor/outdoor scooter that provides transportation for a disabled or elderly person. | The FR-L05 (Luggie Super) provides transportation for an elderly or disabled person. It can be used in a variety of indoor and outdoor settings. | Similar |
| Prescription Use or Over-the-counter Use | Over-the-counter Use | Over-the-counter Use | Same |
| The generic name of the device | Electric scooter | Electric scooter | Same |

| **Category** | **C.T.M. Mobility Scooter, HS-115 New device** | **Freerider Corporation Scooter #Luggie Super K151944** | **Result of Comparasion** |
|---|---|---|---|
| Classification name | 890.3800 Motorized 3-wheeled vehicle | 890.3800 Motorized 3-wheeled vehicle | Same |
| Product Code | INI | INI | Same |

**Non-clinical tests**

The safety tests, such as biocompatibility and electrical safety have been performed and meet the requirement of following FDA Recognized Consensus Standards.

| | | |
|---|---|---|
| ● ISO | 10993-5 | Part 5: Test for in vitro cytotoxicity |
| ● ISO | 10993-10 | Part 10: Tests for irritation and skin sesnitization |
| ● EN | 60601-1:2006 +A11:2011 + A1:2013 + A12:2014 | Part 1: General Requirements for basic safety and essential performance |
| ● IEC | 60601-1-2 | Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests |
| ● ISO | 7176-14 | Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods |
| ● ISO | 7176-21 | Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers |
| ● ISO | 7176-25 | Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs |

Regarding the performance, the bench tests were performed in accordance with following FDA Recognized Consensus Standards. All tests passed the requirement to demonstration that new device is as substantial equivalent as the predicate device.

- ISO 7176-1 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
- ISO 7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- ISO 7176-6 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-7 Wheelchairs - Part 7: Measurement of seating and wheel dimensions

- ISO 7176-8 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-9 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- ISO 7176-10 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ISO 7176-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- ISO 7176-16 Wheelchairs - Part 16: Resistance to ignition of postural support devices
- ISO 7176-22 Wheelchairs - Part 22: Set-up procedures

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**Clinical study**

This 510(k) submission does not utilize clinical study for establishing substantial equivalence therefore this section does not apply.

**Conclusions:**

C.T.M. Mobility Scooter, HS-115 has the same intended use and similar technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any different questions of safety or effectiveness. Thus, C.T.M. Mobility Scooter, HS-115 is substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics.