



Food and Drug Administration
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May 3, 2017

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

Re: K162952
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: April 21, 2017
Received: April 26, 2017

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Michael J. Hoffmann -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

Indications for Use

510(k) Number (if known)

K162952

Device Name

C.T.M. Mobility Scooter

Indications for Use (Describe)

The C.T.M. Mobility Scooter HS-328 is 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.

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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: 2017.4.24

Device Name:

Trade Name: C.T.M. Mobility Scooter, HS-328
Classification Name: Motorized three-wheeled vehicle
Regulation Number: 890.3800
Product Code: INI
Device Class: Class 2
Panel: Physical Medicine

PREDICATE DEVICE:

K070603, C.T.M. Mobility Scooter #HS-295

Indications for Use (IFU) statement:

The C.T.M. Mobility Scooter HS-328 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

Device Description

The C.T.M. Mobility Scooter HS-328 is an indoor/outdoor scooter that is powered by two 22Ah lead-acid batteries, equipped with four pneumatic wheels, capacity of 136 kilograms and a lightweight adjustable seat. It is a rear wheel drive scooter with theoretical driving ranges of 17.5 kilometers. 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.

Substantial Equivalence Comparison

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The C.T.M. Mobility Scooter, HS-328 and the C.T.M. Mobility Scooter #HS-295 have same intended use and classification name/ product code.

The C.T.M. Mobility Scooter, HS-328 and the C.T.M. Mobility Scooter #HS-295 have similar design features. Regarding the HS-328, the dimensions is bigger and heavier, but not significantly. Both scooters have same 4 wheels, rear-wheel drive technology, Electro-Mechanical brakes, Weight of Heaviest Piece, 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 s 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. It is operated exactly the same way as HS-295 during riding and functions on similar ideology and theories.

The new HS-328 with its built in modern technologies for improvements in effectiveness and safety, in many comparable criterions, considered fairly similar to its predicate devices: HS-295.

Furthermore, the new HS-328 has been also tested and certified by relevant required ANSI/RESNA, ISO, IEC standards which are included in this submission.

All comparison table for applied devices are as following, and the substantial equivalence determination is based on the 510(k) Substantial Equivalence Decision-Making Process Flowchart which includes the comparison and discussion of indications for use, technology, and performance specifications.

Category	C.T.M. Mobility Scooter, HS-328 New device	C.T.M. Mobility Scooter #HS-295 K070603	Result of Comparasion
Indications for Use (IFU) statement	The C.T.M. Mobility Scooter HS-328 in an indoor/outdoor scooter that provides transportation for a disabled or elderly person.	The C.T.M. Mobility Scooter HS-295 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.	Same
The generic name of the	Electric scooter	Electric scooter	Same



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Category	C.T.M. Mobility Scooter, HS-328 New device	C.T.M. Mobility Scooter #HS-295 K070603	Result of Comparasion
device			
Classification name	890.3800 Motorized 3-wheeled vehicle	890.3800 Motorized 3-wheeled vehicle	Same
Product Code	89 INI	89 INI	Same
Device Features			
Overall Length	1120 mm / 44"	1013 mm /39.8"	Different
Overall Width	590 mm / 23.2"	509 mm /19.9"	Different
Overall Height	935 mm / 36.8"	887 mm /34.9"	Different
Product weight With battery	55 kg / 121.3 lbs	49 kg / 109 lbs	Different
Weight Of Heaviest Piece	17 kg / 37.5 lbs	17.8 kg / 39.2 lbs	Different
Color of Cover	Ice Blue, Burgundy and Silver	Burgundy 、 Silver 、 Blue	Different
Dismantle for transport?	Yes	Yes	Same
Drive technology	Rear-wheel drive	Rear-wheel drive	Same
Suspension	Rear (Option)	N/A	Different
Motors – Number Size	1 250W, 4000 r.p.m	1 250W, 4600 r.p.m	Different
Brake	Electro-Mechanical	Electro-Mechanical	Same
Braking distance	1.3m/51.2”	1.7m/66.9”	Different
Wheels number	4	4	Same
Front Wheels	225 mm / 9"	200 mm / 8"	Different
Rear Wheels	225 mm / 9"	200 mm / 8"	Different
Wheels materials	PU foaming caster Rim Material: PA+GF Tire Type: filling PU rubber	PU foaming caster Rim Material: PA+GF Tire Type: filling PU rubber	Same



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Category	C.T.M. Mobility Scooter, HS-328 New device	C.T.M. Mobility Scooter #HS-295 K070603	Result of Comparasion
Anti-tip wheels	Yes	Yes	Same
Controller	Dynamic Rhino 50	Dynamic Rhino 50	Same
Function of Control panel			
On/off switches	Yes	Yes	Same
Speed Hi/Lo Dial knob	Yes	Yes	Same
Battery gauge indicator	Yes	Yes	Same
Self-Diagnostic Warning Lig	Yes	Yes	Same
Throttle	Yes	Yes	Same
Horn Button	Yes	Yes	Same
Rear Position light	Yes (optional accessory)	No	Different
Battery – Number Type Size weight	2 Rechargeable Sealed Lead-Acid 12V/22Ah 15.5 kg / 34.2 lbs	2 Rechargeable Sealed Lead-Acid 12V/12Ah 10.4 kg / 23 lbs	Different
Battery charger Availability Size Power	Off-board 24V/5A 100-240V AC	On board 12V/2A 100-240V AC	Different
Battery life cycle	● 100% Depth of Discharge 200cycles ↑ ● 80% Depth of Discharge 225cycles	● 100% Depth of Discharge 400cycles ↑ ● 50% Depth of Discharge	Different



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Category	C.T.M. Mobility Scooter, HS-328 New device	C.T.M. Mobility Scooter #HS-295 K070603	Result of Comparasion
	↑ ● 50% Depth of Discharge 500cycles ↑	800cycles ↑ ● 30% Depth of Discharge 2400cycles ↑	
Seat Type	Swivel Light Weight Foldable	Swivel Padded Foldable	Different
Seat Width	460 mm / 18"	434mm / 17"	Different
Seat upholstery materials	Vinyl upholstery & PU foam	Vinyl upholstery & PU foam	Same
Accessaries	IFU, key switch armrests, front basket and Optional Rear Light	IFU, key switch, armrests, and front basket	Different
Use Parameters			
Target population	Elderly and disabled	Elderly and disabled	Same
Suitability	Indoor and outdoor	Indoor and outdoor	Same
Weight bearing Capacity	136 kg / 300 lbs	136 kg / 300 lbs	Same
Electromagnetic Immunity Level	20V/m	20V/m	Same
the maximum distance of travel on the fully charged battery	17.5 km / 10.9 Miles	10 km / 6.2 Miles	Different
Speed limits Forward Slow control High control Reverse	Yes 1kmh/0.6mph 8 kmh / 5 mph 2.7 kmh / 1.7 mph	Yes 1kmh/0.6mph 8 kmh / 5 mph 2.7 kmh / 1.7 mph	Same



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Category	C.T.M. Mobility Scooter, HS-328 New device	C.T.M. Mobility Scooter #HS-295 K070603	Result of Comparasion
Ground Clearance	52 mm / 2"	40 mm / 1.6"	Different
Grade Climbable	8 degree	8 degree	Same
Curb Climbable	40 mm / 1.6"	32.5 mm / 1.3"	Different
Turning Radius	1450 mm / 57.1"	1270 mm / 50"	Different
Storage (especially battery)	-15°C~40°C (5~105°F) and 25%~85%	-15°C~40°C (5~105°F) and 25%~85%	Same
Labeling	● Instructions for use ● Product Brochure ● Product Labels ● Charger box label. ● Carton label.	● Instructions for use ● Product Brochure ● Product Labels ● Charger box label. ● Carton label	same
Packaging	● Charger box with plastic bag: Charger adapter x 1 pc and key x 1 pc ● Carton box.	● Charger box with plastic bag: Charger adapter x 1 pc and key x 1 pc ● Carton box.	Same
Compliance standard			
Biocompatibility	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10	Same
Electrical safety	IEC60601-1	IEC60601-1	Same
EMC	IEC60601-1-2	IEC60601-1-2	Same
Software	IEC62304 (by controller)	IEC62304 (by controller)	Same
performance	ISO7176 series	ISO7176 series	Same



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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.

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 7176-14 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- 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 7176-21 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- ISO 7176-22 Wheelchairs - Part 22: Set-up procedures
- ISO 7176-25 Wheelchairs -- Part 25: Batteries and chargers for powered wheelchairs

Clinical study

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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-328 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 new questions of safety or effectiveness. Thus, C.T.M. Mobility Scooter, HS-328 is substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics.