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510(k) SUMMARY

Submitter's Name: C.T.M. Homecare Product, Inc.
1663 Iowa Ave.
Riverside, CA 92507
909-788-8168

Date summary prepared: September 10, 2003

Device name:

Proprietary name: C.T.M. Mobility Scooter HS-250
Common or usual name: Electric scooter.
Classification name: Motorized three-wheeled vehicle, Class II,
21 CFR 890.3800.

Legally marketed device for substantial equivalence comparison:

C.T.M. Mobility Scooter HS-360 submitted by Warepalmy Enterprise LLC
(USA) and cleared for marketing under 510(k) #K031272.

Description of the device:

The C.T.M. Mobility Scooter HS-250 is an indoor/outdoor electric scooter that is battery operated. It has a base with four wheels with a lightweight seat, armrests, and a front basket. 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 onboard battery charger.

Intended use of device:

The device is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

Technological characteristics:

The device features and use parameters of the HS-250 and the HS-360 are very similar. Both are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter. Use parameters are very similar, varying only slightly with selected parameters, such as the travel range and the grade the scooter can climb.

Testing conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles*, July 1995, were conducted and the results included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

K032919
20F5

SECTION 3 - INTENDED USE

Intended use of device:

The C.T.M. Mobility Scooter HS-250 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

Intended use of predicate device:

The C.T.M. Mobility Scooter HS-360 is an indoor/outdoor scooter that provides transportation for disabled or elderly persons.

Comparison:

The intended uses of the respective products are the same. Each provides increased mobility for one individual, who is also the operator. Each device can be used in indoor and outdoor settings.

The intended use of the C.T.M. Mobility Scooter HS-250 is given on page 1 of the Instruction Booklet as found in Appendix II of this submission. The intended use of the predicate model is given in the Indications for Use sheet from the 510(k), a copy of which can be found in Appendix III.

SECTION 4 - DEVICE INFORMATION

Executive Summary

The C.T.M. Mobility Scooter HS-250 is an indoor/outdoor electric scooter that is battery operated. It has a base with four wheels with a lightweight seat, armrests, and front basket. 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 onboard battery charger.

The C.T.M. Mobility Scooter HS-250 is a new device and is not a modification of a previously cleared device. Numerous electric scooters are currently on the market.

Scooter

The C.T.M. Mobility Scooter HS-250 is a four-wheeled, battery-powered electric scooter. The design of the scooter is quite similar to other electric scooters that are already on the market. The scooter has a sturdy base, which connects the rear-drive wheels and the front casters. The base also contains the motor, provides spaces for the two batteries, and supports the seat. The seat has adjustable armrests and its height can be adjusted. In addition, the front and rear base pieces can be adjusted to allow more legroom. A controller with thumb control levers located at the top of the steering column enables the rider to control the movement of the scooter. The diagrams in Appendix I show the features and dimensions of the subject scooter. Diagram 1 is a representation of the C.T.M. Mobility Scooter HS-250 with the major parts labeled. Diagram 2 shows the HS-250 from different views with major dimensions given.

If desired, the scooter can be disassembled to provide easier transport. There are 4 components: the base unit with attached steering column, the battery pack, the seat, and the front basket. The front wheels are 7" in diameter and the rear wheels are 8" in diameter. The heaviest single component for model HS-250 weighs 27.7 pounds. With batteries, the scooter weighs approximately 107 pounds. Assembly of the scooter is simple and does not require any tools.

In the assembled scooter, the motor and batteries are located in the base unit. The controller is equipped with associated thumb control levers that enable the scooter to be operated with the hands. These controls are found on the top of the steering column. Handlebars protrude from either side of the steering column. These keep the hands in the correct position to operate the controls and to steer. There is a 250 watt, 3800 rpm motor in the base of the scooter. There is a circuit breaker in the electrical line that will trip if electrical circuits are overloaded. Circuit breaker activation usually denotes a temporary event. After a brief rest, the rider can push the circuit breaker and normal operation will usually be restored.

The braking system in the HS-250 model is electric and automatic. It is on the rear wheels only. The brakes are automatically "on" except when the scooter is turned on and the thumb levers are moved away from the neutral position. When

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the thumb levers are released or moved back to neutral, the brakes engage again. If the electrical brake system fails, the brakes will default to the closed or “brakes on” position, thereby stopping the scooter. The braking distance at maximum speed is 4.67 feet.

The C.T.M. Mobility Scooter HS-250 has a free-wheeling device located near the anti-tip wheels. The normal position of the lever is “D”. In this position the electric scooter will not move without turning on the key and having charged batteries. Moving the lever to the position marked “N” allows the scooter to be rolled freely without the key being turned on. This feature is very useful when maneuvering the scooter for battery charging or storage. The scooter is not intended to be ridden at all in this free-wheeling mode.

The electric scooter is controlled by the rider using the hand controls, i.e., the thumb lever controls that are attached to the top of the steering column. The controller unit is a Model PG 45amp S-drive Controller from PG Drives Technology, Inc. This company used to be called Penny & Giles and has been developing controllers for scooters and powered wheelchairs for a number of years. It consists of a controller box, thumb levers, electrical cable, and imbedded software. When both the left and right thumb levers are in their central, neutral position, the scooter is stopped. If the right lever is engaged, the scooter moves forward. If the left lever is engaged, the scooter moves backward. When both left and right thumb levers are released, the levers automatically return to their central or neutral position, and movement of the scooter ceases. The actual speed at which the scooter moves in a forward or reverse direction depends on speed control dial setting and is proportional to the extent of displacement of the respective thumb lever. To turn the scooter, the steering column is moved in the direction of the desired turn. The minimum turning radius for model HS-250 is approximately 35.4 inches.

The battery charger is onboard in the base unit. Recharging the batteries occurs when the battery charger cable is plugged into both the battery charger and a standard electrical outlet. The scooter will not move unless the key is turned to ON and the batteries are charged.

On the control panel there are multiple controls. See Diagram 3 in Appendix I for locations. These controls include the on/off key, speed dial, battery level indicator, self diagnostic warning light, and horn button. The forward speed range is 0-4.1 mph. The reverse speed range is 0-1.5 mph. The speed dial is used to select an appropriate speed within each of these ranges. The speed dial has a rabbit at one end, indicating higher speed, with a turtle at the other end that represents lower speed. Turning the speed dial toward the turtle reduces the maximum speed within the speed range. Turning it toward the rabbit increases the maximum speed.

The battery level indicator, also called the battery gauge, shows the battery reserve. It consists of a series of yellow lights above three color ranges: red,

K032919
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yellow, and green. When the light is steady and lit in all three color ranges, the batteries are fully charged. When the light is steady, but lit only in the red and yellow zones, the batteries should be recharged as soon as possible.

Located next to the battery level indicator is a separate self-diagnostic warning light that flashes to indicate selected problems with the scooter. Generally speaking, the scooter cannot be driven when this light is flashing. The number of flashes helps determine the problem. The self-diagnostic signals are:

<u>Number of flashes</u>	<u>Problem</u>
1	battery needs recharging
2	battery voltage too low to operate scooter
3	battery voltage too high
4	short in motor
5	brake malfunction
6	transmission lever not in neutral
7	transmission lever malfunction
8	motor problems
9	other internal errors

Detailed explanations of these problems and solutions to them are given in the Troubleshooting section of the Instruction Booklet for the electric scooter, which can be found in Appendix II, beginning on page 31.

Batteries

The C.T.M. Mobility Scooter HS-250 runs on two 12-volt 12Ah batteries. These batteries are provided with the scooter. Replacements can be obtained from the distributor or other local sources.

Battery Charger

A battery charger is onboard. It is a 24-volt constant current charger. It plugs into a standard 110 volt wall socket or into a 220 volt socket.

Accessories

There are no accessories for the C.T.M. Mobility Scooter HS-250.

Regulatory Status

The C.T.M. Mobility Scooter HS-250 is a new device that has not been previously submitted to the FDA.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

C.T.M. Homecare Product, Inc.
C/o Mr. Robert S. McQuate
President
R.S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, AZ 85032

Re: K032919
Trade/Device Name: C.T.M. Mobility Scooter HS-250
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: September 12, 2003
Received: September 22, 2003

Dear Mr. McQuate:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

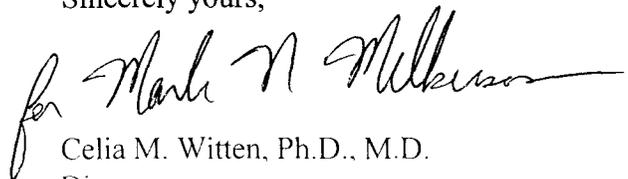
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Page 2 – Mr. Robert S. McQuate

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned above the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device name: C.T.M. Mobility Scooter HS-250

Indications for Use:

The C.T.M. Mobility Scooter HS-250 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

for Mark A. Millerson

(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K032919