

DEC 18 1998

510(k) SUMMARY

Submitter's Name: Warepalmy Enterprise LLC (USA)
1725 NE Orenco Station Parkway
Hillsboro, OR 97124
(503) 693-6516

K983663

Date summary prepared: October 6, 1998

Device name:

Proprietary name: C.T.M. Mobility Scooter HS-666
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:

Shoprider™-TE889 submitted by Pride Health Care, Inc. and cleared for marketing under 510(k) #K920654.

Description of the device:

The C.T.M. Mobility Scooter HS-666 is an indoor/outdoor three-wheeled scooter which is battery operated. It consists of a platform which connects the wheels, an adjustable steering column, and a seat for the rider. The rider drives the scooter using hand controls located at the top of the steering column. It can be disassembled into five parts for transport in a car trunk. It comes with a 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 C.T.M. Mobility Scooter HS-666 and Shoprider scooters are very similar. Both are battery operated, have motors less than 1 horsepower, and have automatic braking systems. Batteries and battery chargers are similar and are provided with the scooters. Use parameters are very similar, varying only in minor parameters such as the curb climbability of the respective scooters.

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).

SECTION 3 - INTENDED USE

Intended use of device:

The C.T.M. Mobility Scooter HS-666 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

Intended use of predicate device:

The Shoprider-TE889 is a motorized scooter designed to be used indoors and outdoors by an elderly or disabled person.

Comparison:

The intended uses of the two 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.

Labeling:

The intended use of the C.T.M. Mobility Scooter HS-666 is stated on page 4 of the Instructions for Use found in Appendix II. The intended use of the Shoprider can be inferred from the Instructions for Use and the promotional material. These can be found in Appendix IV.

SECTION 4 - DEVICE INFORMATION

Executive Summary

The C.T.M. Mobility Scooter HS-666 is an indoor/outdoor three-wheeled scooter which is battery operated. It has a base which connects the three wheels, an adjustable steering column, and a seat for the rider. It is driven by the rider using hand controls located at the top of the steering column. It can be disassembled into five parts for transport. It is provided with a battery charger.

The C.T.M. Mobility Scooter HS-666 is a new device, not a modification of a previously cleared device. Numerous motorized scooters are currently on the market.

Device Description

Scooter

The C.T.M. Mobility Scooter HS-666 is a battery-powered scooter with three wheels. Its design is similar to many other models on the market. Its main parts are a platform base which connects the front and rear wheels, an adjustable seat, and a steering column with control panel. It also has a detachable front basket. The scooter is designed for one person and can be used indoors or outdoors. Diagrams illustrating the scooter features are included in Appendix I. Diagram 1 shows a side view of the scooter with all major parts labeled. Diagram 2 shows front, rear, and side views of the C.T.M. Mobility Scooter HS-666 with major dimensions given.

The scooter can be disassembled for transportation into five components: the rear drive unit, the front platform unit which includes the steering column, the seat, and the two batteries. The heaviest part is the rear unit which weighs 57.5 lbs. The whole scooter with the batteries weighs 179.7 lbs; 129 lbs. without batteries. Assembly of the scooter does not require any tools. The wheel and tire assemblies are 11" in diameter.

The electrical cables run from the control panel, through the steering column, under the platform, and to the batteries. When assembling the scooter, electrical connections must be made between the front and rear units. Each battery must be connected to the electrical system. There is also a circuit breaker in the line.

All controls for the scooter are located at the top of the steering column and are operated with the hands. Diagram 3 in Appendix I shows the controls 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. The whole steering column is turned in the direction that the operator wants to go. The minimum turning radius of the scooter is 100 cm. Just inside the handlebars are two thumb-control levers. Pushing these levers allows the scooter to move.

The right lever moves the scooter forward; the left one moves it backward. As soon as either thumb control lever is released, the brake engages. On the back of the steering column are the key hole and the charger plug-in. The battery charger plugs directly into the steering column to recharge the batteries.

On the control panel there are buttons for sounding the horn, turning on/off the headlight, and signaling turns. There is also a speed dial with a rabbit indicating higher speed at one end and a turtle representing lower speed at the other end. Maximum forward speed on a flat surface is 5.5 mph. Maximum speed in reverse is 2.2 mph. Turning the speed knob to the turtle picture reduces the speed to 2.2 mph in the forward direction and to 0 in the reverse direction. There is a power reserve indicator which shows the battery reserve. Below this light are red, yellow, and green color zones. When this light is completely lit, the batteries are fully charged. When the light is lit only in the red and yellow zones, the batteries should be recharged as soon as possible.

There is also a self-diagnostic warning light which blinks to indicate selected problems with the scooter. Generally speaking, the scooter can not be driven when the self-diagnostic light is flashing. The number of flashes helps determine the problem. When the light is making only one flash, indicating low batteries, the scooter can still be driven. The self-diagnostic signals are:

<u>Number of flashes</u>	<u>Problem</u>
1	battery needs recharging
2	dead battery
3	battery overcharge
4	electrical short
5	brake problem
6-9	electrical system malfunctions

Explanations of the problems and solutions are described in the Instructions for Use for the scooter, which are included in Appendix II.

The braking system is electric. It is on the rear wheels only. The cables for this system run from the steering column to the rear unit. The brakes are automatically "on" except when one of the thumb-control levers is being pushed. Only under these conditions will the brakes disengage. Release of the thumb-control levers engages the brake. Braking time is less than 1 second and braking distance is less than 1 meter. If the electrical brake system fails, the brakes will default to the closed or "brakes on" position, thereby stopping the scooter. A diagram of the brakes is in Diagram 4 in Appendix I.

There is also a free-wheeling device on many scooters. On the C.T.M. Mobility Scooter HS-666 it is located near the base of the seat post. The normal position of

the lever is "D". In this position the 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.

Batteries

The C.T.M. Mobility Scooter HS-666 runs on two 12 volt SLA (sealed lead acid) or gel cell batteries. These batteries are provided with the scooter. Replacements can be obtained from the distributor or other local sources.

Battery Charger

The battery charger is also provided with the scooter. It is a 24 volt constant current charger. It plugs into a standard 110 volt wall socket or into a 220 volt socket.

Accessories

Optional accessories include: a rear basket, a storage cover, a cane holder, and a mirror.

Regulatory Status

The C.T.M. Mobility Scooter HS-666 is a new device which has not been previously submitted to the FDA.



DEC 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert S. McQuate
R.S. McQuate & Associates, Inc.
Representing Warepalmy Enterprise LLC (USA)
3636 East Columbine Drive
Phoenix, Arizona 85032

Re: K983662
Trade Name: C.T.M. Mobility Scooter HS-686
K983663
Trade Name: C.T.M. Mobility Scooter HS-666
Regulatory Class: II
Product Code: INI
Dated: November 12, 1998
Received: November 13, 1998

Dear Mr. McQuate:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does

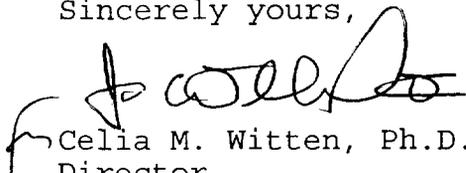
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosures

Indications for Use Statement

510(k) Number (if known): _____

Device name: C.T.M. Mobility Scooter HS-666

Indications for Use:

The C.T.M. Mobility Scooter HS-666 is an indoor/outdoor scooter which provides transportation for a disabled or elderly person.

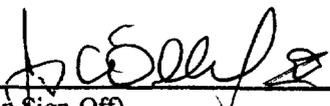
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____

 K983663