

JUL - 6 2009

10090735

## 510(k) SUMMARY

Submitter's name: C.T.M. Homecare Product, Inc.  
6191 Schaefer Ave., Suite B, Chino, CA 91710

Contact name and address: Linda J. Bovard, Bovard Consulting, LLC  
29611 Simmons Road, Eugene, OR 97405  
(541) 345-5431

Date summary prepared: 3/16/09

### Device name:

Proprietary name: C.T.M. Mobility Scooter HS-528 or Leo  
Common or usual name: Electric scooter  
Classification name: Motorized three-wheeled vehicle (890.3800). Motorized  
3-wheeled vehicle (89 INI).

### Legally marketed device for substantial equivalence comparison:

The predicate device is the Victory, 4 Wheel Scooter, Model #SC1740 submitted by  
Pride Mobility Products Corp. and cleared for marketing under 510(k) #K071949.

### Description of the device:

The C.T.M. Mobility Scooter HS-528 is an indoor/outdoor scooter that is battery  
operated. It has a base with four wheels, a padded seat with adjustable armrests, and  
hand controls at the top of the steering column allowing the rider to control the scooter.  
It can be disassembled for transport and is provided with an off-board battery charger.

### Intended use of device:

The C.T.M. Mobility Scooter HS-528 is an indoor/outdoor scooter that provides  
transportation for a disabled or elderly person.

### Technological characteristics:

The device features of the C.T.M. Mobility Scooter HS-528 and the Victory Scooter are  
very similar. Both are battery operated, have one motor, and have automatic braking  
systems. Off-board battery chargers are provided with both scooters. Both scooters can  
be disassembled for transport. The target population is identical and the use parameters  
are similar.

### Testing conducted:

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

### Performance testing:

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

C.T.M. Homecare Product, Inc.  
% Bovard Consulting LLC,  
Ms. Linda J. Bovard  
29611 Simmons Road  
Eugene, Oregon 97405

JUL - 6 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K090735

Trade/Device Name: C.T.M. Mobility Scooter HS-528  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized three-wheeled vehicle  
Regulatory Class: II  
Product Code: INI  
Dated: May 8, 2009  
Received: May 11, 2009

Dear Ms. Bovard:

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.

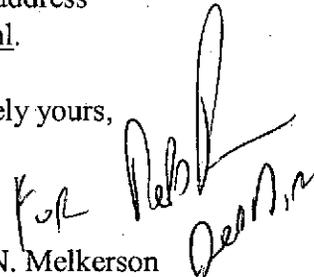
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M" and "N".

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: C.T.M. Mobility Scooter HS-528

Indications for Use:

The C.T.M. Mobility Scooter HS-528 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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