K110567

510(k) SUMMARY

APR 2 2 2011

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

Contact name and address: Sheila Ramerman
927 Throne Drive
Eugene, OR 97402
541-683-3017

Date summary prepared: 2/24/2011

Device name:

Proprietary name:	C.T.M. Mobility Scooter HS-515 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 Three Wheel Scooter, Model SC610 submitted by Pride Mobility Products Corp. and cleared for marketing under 510(k) #K072165.

Description of the device:

The C.T.M. Mobility Scooter HS-515 is an indoor/outdoor scooter that is battery operated. It has a base with three 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-515 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-515 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. The controllers are different.

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).

Substantial Equivalence:

The HS-515 and the predicate device have the same regulatory classification and the same intended use, and similar technological characteristics. Non-clinical testing and specification comparison demonstrate that any differences in specifications or technology do not raise new questions of safety or effectiveness. The HS-515 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C.T.M. Homecare Product, Inc.
% SJR Associates
Ms. Sheila Ramerman
927 Throne Drive
Eugene, Oregon 97402

APR 2 2 2011

Re: K110567
Trade/Device Name: C.T.M. Mobility Scooter HS-515
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: February 25, 2011
Received: February 28, 2011

Dear Ms. Ramerman:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for

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-515

Indications for Use:

The C.T.M. Mobility Scooter HS-515 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K110567