K091418

JUL - 6 2009

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: 5/11/09

Device name:

Proprietary name:	C.T.M. Mobility Scooter HS-628 or Orion
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 C.T.M. Mobility Scooter HS-890 submitted by C.T.M. Homecare Product, Inc. and cleared for marketing under 510(k) #K030387.

Description of the device:

The C.T.M. Mobility Scooter HS-628 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 is provided with an off-board battery charger.

Intended use of device:

The C.T.M. Mobility Scooter HS-628 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-628 and the HS-890 are very similar. Both are battery operated, have one motor, and have automatic braking systems. Off-board battery chargers are provided with both scooters. 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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL - 6 2009

Re: K091418
Trade/Device Name: C.T.M. Mobility Scooter HS-628
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: May 11, 2009
Received: May 13, 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.

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,

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-628

Indications for Use:

The C.T.M. Mobility Scooter HS-628 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 K091418