K073686

FEB 27

510(k) SUMMARY

Submitter's name: C.T.M. Homecare Product, Inc.
13825 Norton Ave., Chino, CA 91710

Contact name: Linda J. Bovard, Bovard Consulting, LLC, Eugene, OR
(541) 345-5431

Date summary prepared: December 24, 2007

Device name:

Proprietary name: C.T.M. Power Chair HS-1500
Common or usual name: Power chair
Classification name: Powered wheelchair (890.3860). Powered wheelchair (89 ITI)

Legally marketed device for substantial equivalence comparison:

The predicate device for this submission is the Alanté submitted by Golden Technologies, Inc. and cleared for marketing under 510(k) #K011153.

Description of the device:

The C.T.M. Power Chair HS-1500 is an indoor/outdoor powered wheelchair that is battery operated. It has a base with four wheels, a padded seat with adjustable armrests, and a controller attached to one armrest which allows the rider to control the movement of the chair. It can be disassembled for transport and is provided with an on-board battery charger.

Intended use of device:

The C.T.M. Power Chair HS-1500 is an indoor/outdoor powered wheelchair that provides transportation for a disabled or elderly person.

Technological characteristics:

The device features of the C.T.M. Power Chair HS-1500 and the Alanté are very similar. Both are battery operated, have two motors, and have automatic braking systems. Battery chargers are provided with both wheelchairs, but the HS-1500 charger is on-board. Both power chairs can be disassembled for transport, but the HS-1500 does not require any tools. 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 Powered Wheelchairs, 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

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

Re: K073686
Trade/Device Name: C.T.M. Power Chair HS-1500
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: 89ITI
Dated: December 24, 2007
Received: December 28, 2007

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.

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.

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological 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. Power Chair HS-1500

Indications for Use:

The C.T.M. Power Chair HS-1500 is an indoor/outdoor powered wheelchair 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 General, Restorative, and Neurological Devices

510(k) Number K060736 K6