K032918

OCT - 6 2003

510(k) SUMMARY

Submitter's Name: C.T.M. Homecare Product, Inc.
1663 Iowa Ave.
Riverside, CA 92507
909-788-8168

Date summary prepared: September 10, 2003

Device name:

Proprietary name:	C.T.M. Mobility Scooter HS-235
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:

C.T.M. Mobility Scooter HS-120 submitted by C.T.M. Homecare Product, Inc. and cleared for marketing under 510(k) #K031272.

Description of the device:

The C.T.M. Mobility Scooter HS-235 is an indoor/outdoor electric scooter that is battery operated. It has a base with three wheels with a lightweight seat, armrests, and a front basket. The movement of the scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard 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 HS-235 and the HS-120 are very similar. They vary only in parameters like dimensions and the size of the motor. Both are electric scooters that are battery operated and have automatic braking systems. Batteries and battery chargers are provided with each scooter.

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).

V. Clinical Performance Evaluations
Clinical performance evaluations are not necessary to demonstrate substantial equivalence to the predicate device.

VI. Conclusion
In summary, based on a comparison of regulatory issues, device features, and use parameters, the C.T.M. Mobility Scooter HS-235 is substantially equivalent to the C.T.M. Mobility Scooter HS-120.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2003

C.T.M. Homecare Product, Inc.
c/o Mr. Robert S. McQuate
President
R.S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, AZ 85032

Re: K032918
Trade/Device Name: C.T.M. Mobility Scooter HS-235
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: September 12, 2003
Received: September 22, 2003

Dear Mr. McQuate:

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.

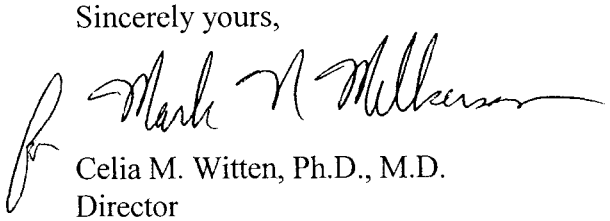
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device name: C.T.M. Mobility Scooter HS-235

Indications for Use:

The C.T.M. Mobility Scooter HS-235 is an indoor/outdoor scooter that provides transportation for a disabled or elderly person.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milham

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032918

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)