K080288

Exhibit 1

Mega Motion, Inc.

Products for Better Living

Travel Pal 4 Wheel Scooter
510(k) Summary

Submitter's Name & Address:	Mega Motion, Inc. 957 Wood Street Old Forge, Pa. 18518 Phone: (888) 415-1200 Facsimile: (888) 415-1210
Contact Person:	Tom Amico Official Correspondent
Date Prepared:	01-29-08
Name of Device and Proprietary Name:	Travel Pal Four Wheel Scooter / Mega Motion
Common or Usual Name:	Four - Wheel Power Scooter
Classification Name:	Vehicle, Motorized 3 - Wheeled
Product Code:	INI

Device Description:
The Travel Pal Four - Wheel Scooter is a battery-operated compact scooter equipped with a digital controller. Features include an adjustable and removable molded plastic seat, a foldable tiller, one-piece solid frame, and an off board charger, designed for ultimate performance, stability and portability. Additional features include electronic regenerative / electromechanical disc brakes, and rear anti-tip wheels designed for ultimate safety.
The Travel Pal Four Wheel Scooter is to be marketed for, but not limited to Mega Motion, Inc. providers / retailers and their consumers.

Comparison to Predicate Device:
The Travel Pal Four Wheel Scooter is a four-wheel version of the Mega Motion, Travel Pal Three Wheel Scooter (K060697) having similar components to justify substantial equivalence. The additional front wheel increases stability, however, components and performance characteristics are identical to the three wheel model, and achieve the same intended use function.

Mega Motion, Inc.

Products for Better Living

Intended Use:

The intended use of the Mega Motion, Inc, Travel Pal Four Wheel Scooter is to provide mobility to persons that have limited walking capabilities or simply those who wish to ride a scooter for transportation purposes.

Non-Clinical Testing:

Compliance to applicable Testing Standards is as follows:
ANSI/RESNA WC/01 Determination of Static Stability
ANSI/RESNA WC/02 Determination of Dynamic Stability
ANSI/RESNA WC/03 Effectiveness of Brakes
ANSI/RESNA WC/04 Determination of Energy Consumption – Theoretical Range
ANSI/RESNA WC/05 Overall Dimensions, Mass & Turning Space
ANSI/RESNA WC/08 Test methods for Static, Impact and Fatigue Strengths
ANSI/RESNA WC/09 Climatic Tests
ANSI/RESNA WC/10 Obstacle Climbing
ANSI/RESNA WC/14 Power and Controls
ANSI/RESNA WC/15 Documentation and Labeling
ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.
ANSI/RESNA WC/93 Maximum Overall Dimensions
CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The Travel Pal Four Wheel Scooter has the same intended use and similar technological characteristics as the Travel Pal Three Wheel Scooter (K060697), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Travel Pal Four Wheel Scooter is substantially equivalent to the Travel Pal Three Wheel Scooter predicate device. The Travel Pal Four Wheel Scooter has passed all the necessary testing procedures and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2008

Mega Motion, Inc.
c/o Mr. Tom Amico
957 Wood Street
Old Forge, PA 18518

Re: K080288
Trade/Device Name: Travel Pal – Four Wheel Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: January 29, 2008
Received: February 4, 2008

Dear Mr. Amico:

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: Travel Pal – Four Wheel Scooter

Indications for Use:

The intended use of the Mega Motion Inc., Travel Pal Four Wheel Scooter, is to provide mobility to persons that have limited walking capabilities or simply those who wish to ride a scooter for transportation purposes.

Prescription Use X ***AND / OR*** ***Over-The-Counter Use*** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050628