

APR 14 1999

K982144

P.O. Box 3744
Scranton, PA 18505-0744
Phone: 1-888-415-1200
Fax: 1-888-415-1210

Mega Motions, Inc.

510(k) Summary

a)	<p>(1) Submitter's name & address:</p> <p>Mega Motion, Inc. P.O. Box 3744 Scranton, PA 18505-3744</p> <p>Date of preparation of this summary:</p> <p>June 15, 1998</p> <p>(2) Device trade or proprietary name Device common or usual name or classification name: Classification Number:</p> <p>Mega 4 scooter 4-wheel power scooter 89INI</p>	<p>Contact person:</p> <p>Paul Gronka Official Correspondent 1-888-415-1200</p>
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(3) Substantial Equivalence:
The Mega 4 power scooter is substantially equivalent in safety, efficacy, technology, and intended use to the Pace Saver Eclipse Premier, currently marketed by Leisure Lift.

(4) Description of the new device:

The Mega 4 is a four-wheel power scooter designed to help people with poor mobility lead a more active lifestyle. The fact that this is a 4-wheel scooter with a two wheel front end provides for a very stable ride. The Mega 4 scooter is an ideal outdoor scooter capable of traversing bumpy or uneven terrain.

The Mega 4 is a four-wheel scooter with exceptional handling and is quiet due to the use of pneumatic tires and a sealed transaxle as opposed to a separate motor, differential, and chain application. It is equipped with two kinds of brakes: dynamic regenerative and a parking brake. The electronic parking brake is normally on and is released when the driver moves the throttle lever. When the driver releases the throttle lever, the regenerative braking will slow the scooter to a stop and the parking brake will be activated 1/2 second thereafter, holding the scooter, preventing any movement. The electronic controller of the Mega 4 has a water-resistant casing with no exposed wires. This feature protects the electronics from environmental damage and corrosion.

The Mega 4 Scooter's maximum forward speed is 5.0mph. The maximum speed in reverse is 60% of the maximum forward speed or 3.0mph. The speed in reverse is reduced for safety purposes as it is more difficult to negotiate a scooter in reverse motion than in forward motion. The speeds are regulated by two devices: a throttle lever and a speed potentiometer.

The Mega 4 has several user-friendly features. It comes equipped with an external freewheeling release lever, external battery charger jack, and an external circuit breaker reset button all for easy accessibility. It has a special light-weight-seat (21 lbs.) for easy

disassembly and transportation. The seat is adjustable up and down, swivels 360°, and has flip up arms. The Mega 4 is equipped with two lateral and two rear high visibility reflectors to increase the scooter's visibility. This feature, as well as the anti-tip wheels located 1 ¼" from the ground on the rear of the scooter, provide added safety for the passenger. The Mega 4 has an adjustable tiller for user comfort and easy transportation.

Electromagnetic interference (EMI) is the energy signals given off by any transmitting device such as CB radios and Cellular phones. These signals may cause erratic behavior in other electronic equipment operating nearby. This includes scooters. There is a caution sticker on the tiller to remind the user to use caution when riding the Mega 4 scooter and not to use communication equipment while the scooter is turned on. The Mega 4 has been EMI tested and passed at an immunity level of 20 V/m. While there is no way to tell if the scooter is totally safe, an immunity level of 20V/m (May '94) is generally achievable and useful. The results of the EMI testing performed on the Mega 4 scooter are included in section 6 of the 510(k)-application package.

The Mega 4 scooter has an on board charger as standard equipment. The charger has passed the minimum voltage ground leakage as required by the FDA/U.L. Certification from the charger supplier is included in section 4 of the 510(k)-application package.

The Mega 4 uses two 12-Volt 31 Amp sealed lead acid batteries. Certifications from the battery supplier that the batteries used on the Mega 3 meet the requirements of 49CFR173.159(d) and Special Provision A67 of the IATA Dangerous Goods Regulations for non-spillable batteries and are therefore, unrestricted for transportation by any means are enclosed in section 4 of this 510(k)-application package.

(5) Intended use of the device:

The Mega 4 scooter is intended to help the user achieve a more independent lifestyle by increasing their personal mobility. The Mega 4 scooter is intended for use by people who due to medical reasons, accident, or injury do not have adequate mobility to lead the active lifestyle they want. It is also intended for any person who would simply rather ride a scooter than walk.

(6) Mega 4 Specifications

Length:	47"
Width:	24"
Turning radius:	42"
Maximum Speed:	5.0 mph
Weight capacity:	250 lbs.
Maximum range:	20-25 miles
Tire type (front):	9" x 4" pneumatic
Tire type (rear):	10" x 4" pneumatic
Rear weight:	45 lbs.
Seat weight:	21 lbs.
Base/Tiller weight:	39 lbs.
Battery weight:	24 lbs. (each)
Battery type:	Two 12-Volt 31 amp (sealed)
Battery charger:	On-board

- b) **(1) Summary of nonclinical tests submitted with the premarket notification for the device.**
The Mega 3 power scooter was tested in accordance with the ANSI/RESNA Standard, Wheelchair – Testing of Power and Control Systems for Electric Wheelchair. WC/14, December 1991, parts 00, 01, 02, 03, 05, and 10 and passed. The results of these tests are included in section 6 of this 510(k) application package.

- b) **(2) Summary of clinical tests submitted with the premarket notification for the device.**
No clinical tests were submitted with the premarket notification for the Mega 4 power scooter.

- b) **(3) Conclusions drawn from the clinical and nonclinical trials.**
Analysis of the comparison of design, function, and features of the Mega 4 power scooter to other devices currently legally marketed for the same intended use, together with the results of testing conducted to assess the Mega 4 power scooter's compliance with existing ANSI/RESNA standards for powered wheelchairs demonstrates the Mega 4 to be substantially equivalent to these predicate devices in terms of safety, efficacy, intended use and technology.



APR 14 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Paul Gronka
Official Correspondent
Mega Motion, Inc.
P.O. Box 3744
Scranton, Pennsylvania 18505-0744

Re: K982144
Trade Name: Mega 4
K982145
Trade Name: Mega 3
Regulatory Class: II
Product Code: INI
Dated: January 19 and March 19, 1999
Received: January 21 and March 23, 1999

Dear Mr. Gronka:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does

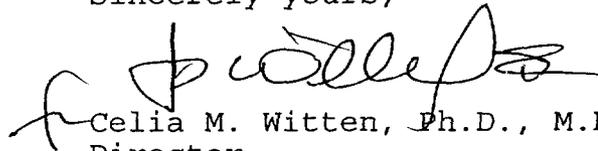
Page 2 - Mr. Paul Gronka

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosures

510(k) Number (if known): K 982144

Device Name: _____

Indications For Use:

To Whom It May Concern:

Indications for Use

The Mega 4 scooter is intended to help the user achieve a more independent lifestyle by increasing their personal mobility. The Mega 4 is intended for use by people who due to medical reasons, accident, or injury do not have adequate mobility to lead the active lifestyle they want. It is also intended for any person who would simply rather ride a scooter than walk.

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FDA/CDRH/ODE/DHC

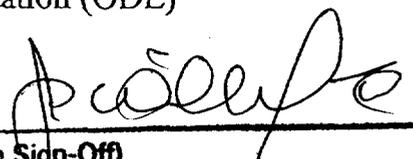
Thank you,



James D. Hill
Assistant to the Official Correspondent

(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 Devices
510(k) Number K982144

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use