"510K SUMMARY" AUG 22 1997

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K972563

CONTACT: DALVA R. ALEXANDER
DATE PREPARED: MARCH 15, 1997

NAME OF DEVICE:	LIFT MASTER SYSTEM
TRADE NAME:	WHEELCHAIR ELEVATOR
PROPRIETARY NAME:	LIFT MASTER
CLASSIFICATION NAME:	PHYSICAL MEDICINE/POWERED WHEEL-CHAIR
PRODUCT CODE:	890-3860

SUBSTANTIAL EQUIVALENCE: PERMOBIL

DESCRIPTION: THE LIFT MASTER CONSISTS OF A BALL DRIVE PEDESTAL ACTUATOR WITH A LOAD CAPACITY OF 500 LBS., ALUMINUM AND STEEL BRACKETS, SAFETY CABLE, AND WIRING HARNESS. THE LIFT MASTER BEGINS WITH A SEAT TO FLOOR HEIGHT OF 17 1/2" AND ELEVATES 8" TO AN UPPER LIMIT OF 25 1/2". OTHER RANGES WILL BE AVAILABLE UPON REQUEST. THE SYSTEM HAS A SPEED REDUCTION CAPABILITY WHILE IN THE LIFTED POSITION. THE LIFT MASTER HAS A WEIGHT LIMIT OF 250 LBS. AND A HEIGHT LIMIT OF 6'. OPERATES ON REAR WHEEL DRIVE AND OFFERS CUSTOM SEATING CAPABILITIES.

INTENDED USE: THE LIFT MASTER ELEVATING POWER SEAT ASSEMBLY DESIGN IS INTENDED FOR USE ON A POWER AND MANUAL WHEELCHAIR. THE LIFT MASTER WILL ELEVATE PATIENTS TO A GREATER HEIGHT THAN THAT OF THE CONVENTIONAL SEAT HEIGHT OF A WHEELCHAIR.

TECHNOLOGICAL CHARACTERISTICS: THE PERMOBIL CHAIRMAN SYSTEM ELEVATES UP TO 8". PERMOBIL BUILDS THEIR OWN LIFTING TOWER, OPERATES ON FRONT WHEEL DRIVE, AND DOES NOT OFFER CUSTOM SEATING CAPABILITIES. MUST USE THEIR OWN MANUFACTURED SEAT. THE LIFT MASTER ELEVATES UP TO 8". THE LIFT MASTER USES AN ACTUATOR BY MOTION, OPERATES ON REAR WHEEL DRIVE AND OFFERS CUSTOM SEATING CAPABILITIES.

NON CLINICAL TESTING: PLEASE REFER TO THE FOLLOWING ATTACHMENT.

LIFT MASTER TESTING

WHEN DRIVEN IN THE RECOMMENDED POSITION, LIFT MASTER HAS THE SAME STABILITY AS THE WHEELCHAIR MANUFACTURER'S HAD BEFORE INSTALLATION OF THE LIFT MASTER.

WHEN DRIVEN IN THE ELEVATED POSITION ON THE TERRAIN OF 0 DEGREES TO 9 DEGREES, IN THE DESIGNATED DRIVE I POSITION WITH THE MAXIMUM WEIGHT LIMIT OF 250 LBS., THE WHEELCHAIR CAN NOT BE TIPPED OR TURNED OVER AS OUR PHYSICAL TESTING HAS SHOWN UNDER THESE CONDITIONS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dalva R. Alexander
Chief Executive Officer
Mechanical Application Designs, Inc.
6819 Highway 90 Boulevard, Suite 680
Katy, Texas 77494

Re: K972563
Lift Master
Regulatory Class: II
Product Code: ITI
Dated: August 11, 1997
Received: August 15, 1997

AUG 22 1997

Dear Ms. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) 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 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 (Premarket Approval), 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 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 device in the Federal Register. Please note: this response to your premarket notification submission does 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 device as described in your 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 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 device, 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

Enclosure

"STATEMENT FOR INDICATION FOR USE"

THE LIFT MASTER ELEVATING POWER SEAT ASSEMBLY DESIGN IS INTENDED FOR USE ON A POWER AND MANUAL WHEELCHAIR. THE LIFT MASTER WILL ELEVATE PATIENTS TO A GREATER HEIGHT THAN THAT OF THE CONVENTIONAL SEAT HEIGHT OF A WHEELCHAIR.

Over-the-Counter Use X

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972563