K992828

p3 1 of 5

FEB 3 2000

"510K SUMMARY"

SUBMITER: Accelerated Rehab Designs, Inc.
32025 Industrial Park Drive
Pinehurst, Texas 77362
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CONTACT: Randall Potter

DATE: 08/18/99

NAME OF DEVICE: E-2000 Power Elevating Seat System

TRADE NAME: E-2000 Power Elevating Seat System

COMMON NAME: Power Elevating Seat System

CLASSIFICATION NAME: Physical Medicine / Wheelchair, Powered

PRODUCT CODE: ITI

REGULATION No: 890.3930

TYPE: Traditional

SUBSTANCIAL EQUIVALENCE:

Mechanical Application Designs, Inc:	Liftmaster	**K972563**

K992802
1 of 2 pages

DESCRIPTION: THE ACCELERATED REHAB DESIGNS, INC "E-2000 POWER ELEVATING SEAT SYSTEM" CONSISTS OF A MOTION SYSTEM, BALL DRIVE TOWER ACTUATOR WITH A LOAD CAPACITY OF 500 POUNDS. THE SYSTEM BRACKETS AND MOUNTING HARDWARE MATERIALS ARE DESIGNED AND MANUFACTURED FROM ALUMINUM AND STEEL. THE E-2000 SYSTEM HAS A BEGINNING SEAT TO FLOOR HEIGHT OF 18 ½ INCHES, AND WILL ELEVATE 8 INCHES TO AN UPPER LIMIT OF 26 ½ INCHES. CUSTOM SEAT TO FLOOR HEIGHTS WILL BE AVAILABLE UPON REQUEST WITH A MAXIMUM ELEVATION OF 28 1/2" INCHES.

THE E-2000 ELEVATING SEAT SYSTEM HAS A WEIGHT LIMIT OF 250 POUNDS, OR THE WHEELCHAIR MANUFACTURES BASE FRAME WEIGHT LIMIT, WHICH EVER IS LOWER. ACCELERATED REHAB DESIGNS WILL NOT EXCEED THE WHEELCHAIR MANUFACTURES BASE FRAME LIMIT.

THE E-2000 SYSTEM IS DESIGNED TO BE DRIVEN IN THE LOWERED POSITION. THERE ARE CERTAIN CIRCUMSTANCES THAT MAY ARRISE THAT A CUSTOMER NEEDS TO DRIVE IN THE ELEVATED POSITION. THIS MAY BE AT WORK, HOME, OR IN THE SCHOOL SETTING. THE WHEELCHAIRS ELECTRONICS ARE TO BE PROGRAMMED TO A VERY SLOW DRIVING SPEED WHILE IN THE ELEVATED POSITION. IF IT IS FELT BY THE REHAB PROFESSIONAL THAT A CUSTOMER SHOULD NOT DRIVE WHILE ELEVATED, A MAGNETIC SWITCH DRIVE LOCKOUT IS INSTALLED. ONCE THE CUSTOMER BEGINS TO ELEVATE, THE WHEELCHAIRS DRIVE CONTROLS ARE DISABLED. ONCE BACK IN THE LOWER POSITION, THE CHAIR MAY BE DRIVEN AGAIN.

BY DESIGN, THE E-2000 SYSTEM WILL ALLOW CUSTOM SEATING SYSTEMS TO BE MOUNTED. THE SYSTEM IS ACTIVATED BY THE USE OF A LOW-AMP DUAL DIRECTION TOGGLE SWITCH.

INTENDED USE: THE E-2000 ELEVATING SEAT SYSTEM DESIGN IS INTENDED FOR USE ON POWER AND MANUAL WHEELCHAIRS. THE SYSTEM WILL ELEVATE CUSTOMERS ABOVE THAT OF THE STANDARD WHEELCHAIR SEAT TO FLOOR HEIGHT. IT ALLOWS THE CUSTOMER TO ACCESS AREAS, WITHOUT THE AID OF AN ATTENDANT THAT HAVE BEEN OUT OF THEIR REACH DUE TO THE STANDARD WHEELCHAIR SEAT TO FLOOR HEIGHT.

TECHNOLOGICAL CHARACTERISTICS: ALTHOUGH SIMILAR IN DESIGN, THE MECHANICAL APPLICATION DESIGNS, TILTMASTER SYSTEM ONLY MOUNTED TO THE INVACARE STORM SERIES BASE FRAME, MAKING THE SELECTION OF WHEELCHAIR BASE FRAMES LIMITING TO THE CUSTOMER. THE E-2000 SYSTEM WILL BE AVAILABLE ON NUMEROUS WHEELCHAIR BASE FRAMES.
HE TILTMASTER SYSTEM WAS REQUIRED TO BE INSTALLED AT THE TILTMASTER MANUFACTURING FACILITY. THE E-2000 SYSTEM IS A DEALER INSTALLATION. ACCELERATED REHAB DESIGN INSTALLATION IS AVAILABLE UPON REQUEST.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2000

Mr. Randall Potter
President
Accelerated Rehab Designs, Inc.
32025 Industrial Park Drive
Pinehurst, Texas 77362

Re: K992828
Trade Name: E-2000 Power Elevating Seat System, Models ARD-ESTORM
Regulatory Class: II
Product Code: ITI
Dated: Undated
Received: December 28, 1999

Dear Mr. Potter:

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) 594-4595. 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,

for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992828

Device Name: **E-2000 POWER ELEVATING SEAT SYSTEM**

Indications For Use:

The "E-2000 Power Tilt Seating System" is an elevating system utilizing the wheelchair manufactures existing tubular seating system with armrests, front rigging, back assembly, and optional accessories.

The Elevating Seat System attaches to the wheelchair base frame and seat frame. By activation of the supplied switch, the system will elevate up to eight (8) inches from its lowest position.

The E-2000 Power Elevating Seat System allows the customer the availability to reach items that in the past, were unreachable to them due to their physical limitations. In the home, the overhead kitchen cabinets are now accessible. In the workplace, the availability of reaching the upper drawers of file cabinets without help from others. Having the ability to interact with fellow students on their level, within the school setting. Some of the customers that may benefit from the use of the E-2000 System are customers with a diagnosis of, but not limited to:

- Muscular Dystrophy (MD)
- Multiple Sclerosis (MS)
- Spinal Cord Injury (SCI)
- Amyotrophic Lateral Sclerosis (ALS)
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Accelerated Rehab designs makes no claims as to the therapeutic effectiveness of the product(s) listed. Accelerated Rehab Designs recommends that an accredited rehabilitation therapist and supplier evaluate all customers of its products.

The above indications for use are identical to those of Mechanical Application Designs, Inc Liftmaster System in which we are claiming substantial equivalence.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992828

Prescription Use:_____ OR Over-The-Counter Use: X
(Pre 21 CFR 801.109) (Optional Format 1-2-96)

Revised 11/13/1998