FEB 3 2000

K993804
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"510K SUMMARY"

SUBMITER: Accelerated Rehab Designs, Inc.
32025 Industrial Park Drive
Pinehurst, Texas 77362
Phone: (281)356-1950
Fax: (281)356-1903
Email: ard@ev1.net

CONTACT: Randall Potter

DATE: 08/13/99

NAME OF DEVICE: T-2000 Power Tilt Seating System

TRADE NAME: T-2000 Power Tilt Seating System

COMMON NAME: Power Tilt-in-Space Seating System, Center of Gravity, Power Tilt in Space System

CLASSIFICATION NAME: Physical Medicine / Wheelchair, Powered

PRODUCT CODE: ITI

REGULATION No: 890.3860

TYPE: Traditional

SUBSTANCIAL EQUIVALENCE:

Motion Concepts: K981837	TRx-CG Center of Gravity Shifting Power Tilt
Mechanical Application Designs: K972564	Tiltmaster Center of Gravity Power Tilt System
Invacare Corporation.	Tarsys Weight Shifting Basic Tilt System

K173804

DESCRIPTION: THE ACCELERATED REHAB DESIGNS "T-2000 POWER TILT SEATING SYSTEM" IS A CENTER OF GRAVITY DESIGN, AFTERMARKET POWER TILT IN SPACE SYSTEM THAT UTILIZES THE WHEELCHAIR MANUFACTURES EXISTING TUBULAR SEAT FRAME, ARMRESTS, FRONT RIGGING, BACK ASSEMBLY AND OPTIONAL ACCESSORIES. THE SYSTEM CONSISTS OF STEEL AND ALUMINUM BRACKETS AND MOUNTING HARDWARE. THE T-2000 SYSTEM UTILIZES A LINEAR ACTUATOR MANUFACTURED BY LINAK CORPORATION, AND HAS A LOAD CAPACITY OF 750 POUNDS. THE LINAK ACTUATOR HAS AN INTERNAL SAFETY NUT ATTACHED TO THE BALL SPINDLE IN THE CASE OF ACTUATOR FAILURE. THIS SAFETY NUT WILL NOT ALLOW THE SEATING SYSTEM TO TILT BACKWARD ANY FARTHER THAN THE FULL STROKE OF THE ACTUATOR. THIS ELIMINATES THE POSSIBILITY OF THE CLIENT TIPPING OVER BACKWARD DUE TO ACTUATOR FAILURE. THE WHEELCHAIR SEAT FRAME IS ATTACHED TO THE WHEELCHAIR BASE FRAME VIA THE T-2000 SYSTEM MOUNTING HARDWARE BRACKETS AND HARDWARE.
THE T-2000 SYSTEM IS ACTIVATED BY A DUAL DIRECTION "LOW-AMP" TOGGLE SWITCH. INCLUDED IN THE WIRING HARNESS IS A LOW-AMP SWITCH INTERFACE BOX THAT WILL ACCEPT MOST INDUSTRY WIDE LOW-AMP SINGLE AND DUAL SWITCHES UTILIZING AN 1/8TH INCH MALE PHONO JACK LEAD.

AS THE TOGGLE SWITCH IS ACTIVATED, THE SEATING SYSTEM WILL BEGIN TO TILT. AS THE SYSTEM IS TILTING, THE SEATING SYSTEM IS ALSO MOVING FORWARD MAINTAINING THE CENTER OF GRAVITY OF THE CLIENT ON THE WHEELCHAIRS BASE FRAME. THIS ALLOWS FOR USE OF SHORTER BASE FRAMES FOR A WIDER RANGE OF INDIVIDUALS. THE HEAVIER, TALLER CLIENT CAN HAVE THE SAME ACCESS AND PERFORMANCE AS THE SMALLER, LIGHTER CLIENT.

THE T-2000 HAS A STANDARD TILT RANGE OF ZERO TO 50 DEGREES. CUSTOM ANGLES ARE AVAILABLE. THERE IS A MINI-MICRO SWITCH ATTACHED TO THE SYSTEMS MOUNTING HARDWARE THAT RESTRICTS THE CLIENT FROM DRIVING BEYOND 20 DEGREES OF TILT.

INTENDED USE: THE ACCELERATED REHAB DESIGNS, INC T-2000 POWER TILT SEATING SYSTEM IS INTENDED FOR THE CLIENT THAT REQUIRES POSITIONING CHANGES DURING THE COURSE OF THE DAY WITHOUT THE AID OF AN ATTENDANT. THIS COULD BE FOR PRESSURE RELIEF, COMFORT ADJUSTMENTS, AND POSITIONING NEEDS.

TECHNOLOGICAL CHARACTERISTICS: THE T-2000 SYSTEM UTILIZES THE LINAK ACTUATOR WHICH HAS A PROVEN TRACK RECORD OF PERFORMANCE, AND RELIABILITY. THE SYSTEM MOVES FORWARD ON THE T-2000 MOUNTING HARDWARE VIA A PAIR OF SELF- CLEANING, LINEAR BEARING GUIDES. BY USE OF THESE GUIDES, THERE IS VERY LITTLE RESISTANCE ASSOCIATED WITH THE TILTING OF THE SYSTEM. THE LINEAR BEARINGS ARE MUCH MORE EFFICIENT THAN CAMS, AND OIL LIGHT ROLLER BEARINGS. THIS INCREASES ACTUATOR LIFE, AND REDUCES STRESS AND FATIGUE ON STRUCTURAL COMPONENTS.

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: K992804
Trade Name: T-2000 Power Tilt Seating System, Models ARD-TSTORM
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 Mark N. Melkerson

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

Enclosure

K992804

510(K) Number (if known): K992804

Device Name: **T-2000 POWER TILT SEATING SYSTEM**

Indications For Use:

The "T-2000 Power Tilt System" is an aftermarket Power Tilt in Space Seating System utilizing the wheelchair manufactures base frame and seat frame. The T-2000 Power Tilt Seating System attaches between the base frame and seat frame of the wheelchair, allowing for the tilting action of the system upon activation of the Low-Amp Toggle Switch or any alternative low-amp switch that the client may choose to operate. The T-2000 system has no software based components. The T-2000 system is appropriate for individuals who require changes in position without the help of an attendant. Power tilt systems are utilized by individuals with a variety of physical disabilities. Some of the indications for use include:

- The reduction of sitting pressure, may prevent Decubitus Ulcers
- Gravity assisted positioning
- Increased sitting stability
- Assistance in feeding, Improved Swallowing
- Increased Respiratory Function
- Decrease Muscle Tone
- Comfort Adjustments

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 the Motion Concepts, Mechanical Application Designs, and Invacare Tarsys Power Tilt in Space Systems 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 Mark N Milhoan

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K992804

Prescription Use: _____ **OR** **Over-The-Counter Use:** X

(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Revised 11/13/1998