

AUG - 1 2001

"510K SUMMARY"

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

CONTACT: Randall Potter
DATE: 07/19/2001

NAME OF DEVICE: TRS-2000 Power Tilt / Power Recline Seating System

TRADE NAME: TRS-2000 Power Tilt / Power Recline Seating System

COMMON NAME: Power Tilt / Recline Seating System,
 Power Tilt / Power Recliner

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
Medical Industries of America K011053	Optima 2000
Invacare Corporation. K991119	Tilt/Recliner for Power Wheelchairs, Model 2G

EACH OF THESE PRODUCTS ARE BATTERY POWER, MOTORIZED SEATING SYSTEMS DESIGNED FOR USE WITH POWERED WHEELCHAIRS. PERFORMANCE CHARACTERISTICS AND DRIVE MECHANISMS ARE SIMILAR AND ALL HAVE THE SAME INTENDED FUNCTION AND USE WHICH IS TO AID IN THE PRESSURE RELIEF OF PERSONS CONFINED TO A POWER WHEELCHAIR, BY PROVIDING A METHOD OF TILTING THE SEAT OR RECLINING THE BACK. THEY ARE ALL CONSTRUCTED FROM THE SAME BASIC MATERIALS, HAVE THE SAME BASIC OPERATIONAL PRINCIPLES AND ALL USE DC BATTERIES AS THEIR SOURCE OF POWER.

DESCRIPTION:

THE ACCELERATED REHAB DESIGNS "TRS-2000 POWER TILT / POWER RECLINE SEATING SYSTEM IS A " CENTER OF GRAVITY "DESIGN, AFTERMARKET POWER TILT IN SPACE / POWER RECLINE SYSTEM (3" RAISED PIVOT POINT) THAT UTILIZES THE ACCELERATED REHAB DESIGNS SEAT FRAME ASSEMBLY.

LISTED BELOW ARE SOME OF THE WHEELCHAIR BASE FRAMES COMPATABLE FOR INSTALLATION OF THE TRS-2000 SYSTEM: (BUT NOT LIMITED TO)

WHEELCHAIR BASE FRAME MODEL

SYSTEM MODEL NO:

- | | |
|------------------------------------|-----------------|
| • INVACARE STORM SERIES WHEELCHAIR | ARD-TRSSTORM |
| ➤ REAR WHEEL DRIVE | ARD-TRSSTORM |
| ➤ MID-WHEEL DRIVE | ARD-TRSSTORM |
| ➤ FRONT WHEEL DRIVE | ARD-TRSSTORM |
| • INVACARE RANGER-II WHEELCHAIR | ARD-TRSRANGERII |
| • INVACARE PRONTO WHEELCHAIR | ARD-TRSPRONTO |
| • INVACARE PRONTO-M6 WHEELCHAIR | ARD-TRSPRONTOM6 |
| • QUICKIE P-222 WHEELCHAIR | ARD-TRSP222 |
| • QUICKIE P-320 WHEELCHAIR | ARD-TRSP320 |
| • QUICKIE S-424 WHEELCHAIR | ARD-TRSG424 |
| • QUICKIE S-525 WHEELCHAIR | ARD-TRSS525 |
| • QUICKIE S-626 WHEELCHAIR | ARD-TRSS626 |
| • PRIDE JAZZY 1100 WHEELCHAIR | ARD-TRSJAZZY |
| • PRIDE JAZZY 1120 WHEELCHAIR | ARD-TRSJAZZY |
| • PRIDE JAZZY 1120-2000 WHEELCHAIR | ARD-TRSJAZZY |
| • PRIDE JAZZY 1170 WHEELCHAIR | ARD-TRSJAZZY |
| • PRIDE JAZZY 1400 WHEELCHAIR | ARD-TRSJAZZY |
| • PRIDE JAZZY 1420 WHEELCHAIR | ARD-TRSJAZZY |
| • PRIDE JAZZY 1470 WHEELCHAIR | ARD-TRSJAZZY |
| • E & J LANCER 2000 WHEELCHAIR | ARD-TRSLANCER |
| • E & J SOLARA WHEELCHAIR | ARD-TRSSOLARA |
| • BRUNO PWC2200 WHEELCHAIR | ARD-TRSPWC2200 |
| • BRUNO PWC2300 WHEELCHAIR | ARD-TRSPWC2300 |
| • SHOPRIDER 888WA WHEELCHAIR | ARD-TRS888WA |
| • SHOPRIDER 888WNL WHEELCHAIR | ARD-TRS888WNL |

THE SYSTEM CONSISTS OF STEEL AND ALUMINUM BRACKETS AND MOUNTING HARDWARE. THE TRS-2000 SYSTEM UTILIZES A LINEAR ACTUATORS MANUFACTURED BY LINAK CORPORATION, AND HAS A LOAD CAPACITY OF 750 POUNDS. THE LINAK ACTUATORS HAVE 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 OR RECLINE BACK 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 TRS-2000 SYSTEM MOUNTING HARDWARE BRACKETS AND HARDWARE.

THE TRS-2000 SYSTEM IS ACTIVATED BY A DUAL DIRECTION "LOW-AMP" TOGGLE SWITCH. INCLUDED IN THE WIRING HARNESS IS A DUAL MOTOR LOW-AMP SWITCH INTERFACE BOX THAT WILL ACCEPT MOST INDUSTRY WIDE LOW-AMP SINGLE SWITCHES UTILIZING AN 1/8TH INCH MALE PHONO JACK LEAD.

AS THE TOGGLE SWITCH IS ACTIVATED IN ONE DIRECTION, 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. ONCE THE POWER TILT SYSTEM PASSES 20 DEGREES OF TILT, THE WHEELCHAIRS DRIVE CONTROLS ARE DISABLED. ACTIVATING THE SWITCH IN THE SAME DIRECTION ONCE AGAIN WILL RETURN THE TILT SYSTEM TO THE FORWARD POSITION. ONCE THE TILT SYSTEM IS RETURNED TO THE FORWARD POSITION, THE DRIVE CONTROLS ARE ENABLED.

ACTIVATION OF THE TOGGLE SWITCH IN THE OPPOSITE DIRECTION WILL ACTIVATE THE POWER REDUCED SHEAR RECLINE SYSTEM. ONCE THE RECLINE ANGLE REACHES 120 DEGREES, THE WHEELCHAIR DRIVE CONTROLS ARE DISABLED. ACTIVATION OF THE SWITCH AGAIN WILL RETURN THE RECLINE TO THE UPRIGHT POSITION. UPON RETURNING TO AN ANGLE LESS THAN 120 DEGREES THE DRIVE CONTROLS ARE ONCE AGAIN ENABLED.

THE REDUCED SHEAR POWER RECLINE SYSTEM HAS A MERCURY SWITCH INCLUDED. THIS SWITCH LIMITS THE AMOUNT OF TILT AVAILABLE WHEN RECLINED. THE GREATER THE RECLINE ANGLE, THE LESS THE AVAILABLE AMOUNT OF TILT REMAINING.

THE TRS-2000 SYSTEM HAS A STANDARD TILT RANGE OF ZERO TO 50 DEGREES. CUSTOM ANGLES ARE AVAILABLE. THE POWER RECLINING BACK ASSEMBLY HAS A RECLINE RANGE FROM 90 TO 155 DEGREES.

THE ACCELERATED REHAB DESIGNS TRS-2000 POWER TILT/ POWER RECLINE SYSTEM HAS NO SOFTWARE BASED COMPONENTS.

INTENDED USE:

THE ACCELERATED REHAB DESIGNS, INC TRS-2000 POWER TILT / POWER RECLINE 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 TRS-2000 SYSTEM UTILIZES THE LINAK ACTUATOR WHICH HAS A PROVEN TRACK RECORD OF PERFORMANCE, AND RELIABILITY. THE SYSTEM MOVES FORWARD ON THE TRS-2000 MOUNTING HARDWARE VIA A PAIR OF SELF- CLEANING, MAINTENANCE FREE 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. THE POWER RECLINE SYSTEM ALSO UTILIZES A LINAK POWER ACTUATOR FOR ACCURATE ANGLE ADJUSTMENTS.

THE TILTING AND RECLINING SYSTEMS ARE SEPARATE MODULES AND ARE INDEPENDENT OF EACH OTHER. THIS ALLOWS FOR THE SYSTEMS TO BE OFFERED AS SEPARATE POWER TILT (ONLY), POWER RECLINE (ONLY), OR POWER TILT/POWER RECLINE COMBINATION DEPENDING ON THE NEEDS OF THE CLIENT.

TESTING:

THERE WAS NO CLINICAL TESTING ASSOCIATED WITH THE TRS-2000 POWER TILT SYSTEM. TESTING AT ACCELERATED REHAB DESIGNS REVEILED THE FOLLOWING RESULTS:

THE FOLLOWING ARE ADDITIONAL FORCES (PRESSURES) REQUIRED BEYOND THE CLIENTS WEIGHT, TO TIP THE TRS-2000 POWER TILT / POWER RECLINE SYSTEM REARWARD ENOUGH TO LIFT THE FRONT CASTERS OFF OF THE FLOOR. THE SEATING DEMINSIONS OF THE SYSTEM TESTED WERE AS FOLLOWS:

- ✓ SEAT WIDTH = 18"
- ✓ SEAT DEPTH = 18"
- ✓ BACK HEIGHT = 24"
- ✓ WEIGHT LOAD = 270 POUNDS

SYSTEM LOCATION (DEGREE OF SYSTEM TILT)	BACK PRESSURE REQUIRED TO LIFT FRONT CASTERS OFF THE GROUND ON A FLAT LEVEL SURFACE	BACK PRESSURE REQUIRED TO LIFT FRONT CASTERS OFF THE GROUND ON A 9 PERCENT GRADE
Zero Degrees of Posterior Tilt Back in the upright position	300 Pounds	217Pounds
50 Degrees of Posterior Tilt Back in the upright position	129 Pounds	65 Pounds
Zero Degrees of Posterior Tilt Back at 175 Degrees	178 Pounds	106 Pounds



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Randall Potter
President
Accelerated Rehab Designs, Inc.
32035 Industrial Park Drive
Pinehurst, Texas 77362

Re: K012281

Trade/Device Name: TRS-2000 Power Tilt/Power Recline Seating System
Regulation Number: 890.3860
Regulatory Class: II
Product Code: ITI
Dated: July 19, 2001
Received: July 20, 2001

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 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). 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 requirements, 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.

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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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(K) Number (if known): K 012281

Device Name: **TRS-2000 POWER TILT / POWER RECLINE SEATING SYSTEM**

Indications For Use:

The "TRS-2000 Power Tilt / Power Recline Seating System" is an aftermarket Power Seating System utilizing the various wheelchair manufacturers base frames and Accelerated Rehab Designs Seat Frame Assembly. The TR-2000 Power Tilt / Power Recline Seating System replaces the existing wheelchair manufacturers seat frame and attaches to the wheelchair base frame allowing for the Tilting and Reclining 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 TRS-2000 System is modular in design and may be added to an existing Power Tilt System, or be a stand alone power recline system.

The TRS-2000 System has no software based electronic components.

The TRS-2000 System is appropriate for individuals who require chances in position without the help of an attendant. Power recline 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, Invacare Corporation, and Medical Industries of America Power Tilt / Recline Seating 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)

Prescription Use: _____
(Per 21 CFR 801.109)

OR

Over -The-Counter Use: _____
(Optional Format 1-2-96)

Revised 11/13/1998

[Handwritten Signature]
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012281