AUG 25

"510K SUMMARY"

K972564

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

NAME OF DEVICE:	TILT MASTER CG SYSTEMS (CENTER OF GRAVITY)		
TRADE NAME:	TILT-N-SPACE CENTER OF GRAVITY SYSTEM		
PROPRIETARY NAME:	CG SYSTEM		
CLASSIFICATION NAME:	PHYSICAL MEDICINE/POWERED WHEELCHAIR		
PRODUCT CODE:	890-3860		
SUBSTANTIAL EQUIVALENCE:	E&J	-	VORTEX TILT-N-SPACE CENTER OF GRAVITY
	FOLIO	-	TS90, TS95
	VECTOR MOBILITY	-	BASE LINK TILT-N-SPACE

DESCRIPTION: THE TILT MASTER CG SYSTEM (CENTER OF GRAVITY), IS AN AFTERMARKET KIT CONSISTING OF A LINEAR ACTUATOR WITH 900 POUNDS CAPACITY, ALUMINUM AND STEEL BRACKETS, WIRING HARNESS TO SUPPLY VOLTAGE TO THE ACTUATOR, AND A MERCURY SWITCH DRIVER LOCKOUT WHICH RENDERS THE WHEELCHAIR INOPERABLE WHEN TILTED BEYOND 15 DEGREES. THE CG SYSTEM KIT IS DESIGNED TO CONVERT A POWERED OR MANUAL STANDARD WHEELCHAIR TO A POWER RECLINE. THE TILT MASTER CG SYSTEM USES A CENTER OF GRAVITY DESIGN TO MOVE THE PATIENTS CENTER OF GRAVITY FORWARD 6" AS THE SYSTEM TILTS. THIS PROVIDES ADDED SECURITY WHEN IN THE TILTED POSITION. THE TILT MASTER CG SYSTEM ALLOWS THE USER TO HAVE 5 TO 55 DEGREE RANGE OF TILT. THE TILT MASTER CG SYSTEM IS DESIGNED SO IF ANY CATASTROPHIC FAILURE OCCURS WHILE THE SEAT IS IN THE TILT POSITION, THE SAFETY NUT ON THE ACTUATOR WILL ALLOW THE DRIVER TO PUT THE SEAT BACK ON THE DRIVE POSITION AND WILL DISABLE THE TILT MECHANISM. THE

DRIVER WILL BE UNABLE TO PUT THE SYSTEM IN THE TILT POSITION ONCE THIS OCCURS.

INTENDED USE: THE TILT MASTER CG SYSTEM DESIGN IS INTENDED FOR USE ON A POWER OR MANUAL STANDARD WHEELCHAIR TO PROVIDE POWER RECLINE FOR POSTERIOR TILT FOR POSITIONING AND SEATING PRESSURE RELIEF.

TECHNOLOGICAL CHARACTERISTICS: THE E&J SYSTEM HAS A LIMIT OF 3" OF LINEAR TRAVEL. THEIR SYSTEM ROLLS ON CAM MEANS (ROLLS ON A MACHINED OUT GROOVE). E&J USES AN ACTUATOR BY MOTION. THE TILTMASTER CG SYSTEM HAS A 6" LINEAR MOTION, HAS AN OIL LIGHT BEARING ROLLER THROUGH A TROUGH MEANS, USES A HIGHER QUALITY MADE ACTUATOR BY LINAK WHICH ALSO HAS AN EXTRA 2 YEAR WARRANTY. TILTMASTER ALSO SENDS OUT A PADDED COUNTOURED BACK AND HEADREST WITH ALL OUR SYSTEMS.

NON CLINICAL TESTING: PLEASE REFER TO THE FOLLOWING ATTACHMENT.

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

AUG 25 1997

Re: K972564
Tilt Master CG System (Center of Gravity)
Tilt-N-Space-Seat
Regulatory Class: II
Product Code: ITI
Dated: March 15, 1997
Received: July 9, 1997

Dear Ms. Alexander:

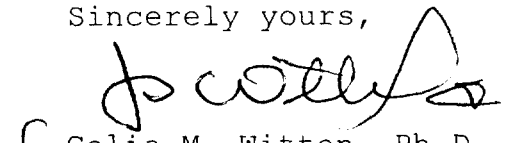
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



for 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 TILTMASTER KIT DESIGN IS INTENDED FOR USE ON A POWER AND MANUAL WHEELCHAIR TO PROVIDE PATIENTS WITH POSTERIOR TILT FOR POSITIONING AND SEATING PRESSURE RELIEF.

Over-the-Counter Use X

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972564