

K991119

AUG 19 1999

**510(k) SUMMARY
INVACARE CORPORATION'S
510(k) PREMARKET NOTIFICATION
MODEL 2G TILT/RECLINER FOR POWER WHEELCHAIRS**

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558
Contact Person: Edward A. Kroll, Director, TQM and Regulatory Affairs
Date Prepared: March 31, 1999

Name of Device and Name/Address of Sponsor
Model 2G Tilt/Recliner for Powered Wheelchairs

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name
Power Wheelchair

Classification Name
Wheelchair, Powered

Predicate Devices
Products which are substantially equivalent to the Model 2G Controls are; Everest & Jennings Power Recliner Wheelchair (K914091, November 19, 1991), the Permobile Chairman (K960951, April 30, 1997), and the LaBac Adjustable Sliding Back Power Recline System (K923363, March 24, 1993).

Intended Use
Its intended function and use is to aid in the pressure relief to persons confined to a powered wheelchair, by way of posterior tilt and reclining seat back.

Technological Characteristics and Substantial Equivalence

A. Device Description
The Invacare Model 2G Power Tilt/Recliner Seating System for Power Wheelchairs is a battery powered, motorized seating system designed for use with power wheelchairs. Its intended function and use is to aid in the pressure relief of persons confined to a wheelchair, by providing a method of tilting the seat and reclining the seat back.

The tilting and reclining systems are separate modules and are independent of each other. As such, they will be offered as either a complete tilt/recline system, or as a separate tilt system or reclining system depending upon the users' needs. The reclining system also includes a movable leg rest feature.

The system includes an upper and lower frame assembly both of which are fabricated from welded steel. The lower assembly mounts directly to the wheelchair base using standard mounting screws. It includes the recline drive actuator as well as other mechanical components used to either tilt or recline the seating system.

The upper frame includes the wheelchair seat and back, as well as the tilt drive actuator. The seat and back are constructed of aluminum plates without upholstery. This allows the wheelchair user to decide the type of seat cushion that best meets their individual needs as determined by the health care provider.

B. Substantial Equivalence

Products which are substantially equivalent to the Invacare Model 2G Tilt/Recline are; Tarsys Engineering Tilt/Recline Seating System (K 911151, March 29, 1991), the Everest & Jennings Power Recliner Wheelchair (K914091, November 19, 1991), the Permobil Chairman (K960951, April 30, 1997), and the LaBac Adjustable Sliding Back Power Recline System (K923363, March 24, 1993).

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 powered wheelchair, by providing a method of tilting the seat and reclining the seat back. Additionally, 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.

PERFORMANCE DATA

The Invacare Model 2G Tilt/Recline Seating System for Power Wheelchairs meets the applicable requirements specified in the Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/14 (1991) and ISO Standard ISO 7176: 1993 (E) "ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1999

Mr. Edward A. Kroll
Director, TQM and Regulatory Affairs
Invacare® Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K991119
Trade Name: Tilt/Recliner for Power Wheelchairs, Model 2G
Regulatory Class: II
Product Code: ITI
Dated: July 26, 1999
Received: July 27, 1999

Dear Mr. Kroll:

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 control provisions of the Act. The general control 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

510(k) Number (if known): *TBD*

Device Name: *Model 2G Power Tilt/Recliner Seating System for Power Wheelchairs*

Indications For Use:

It is intended use is to aid in the pressure relief of persons confined to a power wheelchair, by providing a method of tilting the seat and reclining the seat back..

Mark N. Melburn

*for
OCMW*

(Device Sign-Off)

Division of **General Restorative Devices**

510(k) Number _____

K 991119

(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 X