K013516

P. 1/3

## 510(k) SUMMARY

DEC 1 3 2001

**Invacare Corporation's**
**Invacare Elevating Seat Option**

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

Invacare Corporation
One Invacare Way
PO Box 4028
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: October 19, 2001

**Name of Device and Name/Address of Sponsor**

Invacare Elevating Seat Option

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2028
Phone: (440) 329-6000
Facsimile: (440) 365-4558

**Common or Usual Name**

Elevating Seat

**Classification Name**

Wheelchair, Powered

**Predicate Devices**
Accelerated Rehab Designs, Inc. "E-2000 Power Elevating Seat System" (K992828, 2/3/2000)

**Intended Use**
The intended function and use of the Invacare Elevating Seat is to provide powered elevation of the wheelchair seat and user in order to assist the user with daily activities, transfers and general accessibility.

**Technological Characteristics and Substantial Equivalence**

**A. Device Description**

The Invacare Elevating Seat consists of a pedestal actuator, mounting weldments with mounting hardware, and a toggle control. The intended function and use of the elevating seat is to provide powered elevation of the wheelchair seat and user in order to assist the user with daily activities, transfers and general accessibility.

The bottom of the actuator assembly is mounted to the base of the wheelchair via the seat support weldment, which is specific to the particular wheelchair model. The top of the actuator assembly mounts to the wheelchair seat assembly via the seat mount bracket, which is specific to the seat assembly of the wheelchair. The ball drive pedestal actuator has a load capacity of 500 pounds and a maximum stroke of 8 inches. The elevating seat is available for select models of power wheelchair as a factory installed option.

The MIV Elevating Seat Toggle is standard with the elevating seat option. It is a DC brush type motor controller that is used to control the elevating actuator on power wheelchair systems with the elevating seat option installed. A double throw momentary position switch is used to drive the actuator. Current through the motor is limited and drive speed reduction occurs when the chair is in an elevated position.

The MIV Elevating Seat Toggle connects to the Power Take Off (PTO) connector of the wheelchair battery harness. Therefore, the power supply for the elevating seat toggle is taken directly from the wheelchair battery harness through a 15 amp fused power block, and the elevate function can be activated even when the wheelchair drive controls are turned off.

The MIV Elevating Seat Toggle also connects to a proximity switch, which senses when the seat is elevated. When the switch senses that the seat is elevated more than .75 inches, the speed of the wheelchair is reduced to 20% of the maximum possible speed of the chair. However, the reduced speed will not exceed the user-programmed speed.

**MKIV TAC**

For certain wheelchair models, the MIV TAC, a two-actuator control, is available as an option to the MIV Elevating Seat Toggle. The MIV TAC allows the elevating seat to be combined with the tilt feature of the wheelchair seating system and it allows the elevating seat to be controlled through the joystick of the wheelchair.

In addition to the features described under the MIV Elevating Seat Toggle, the MIV TAC has an additional tilt sensor that detects the overall back angle of the seating system. If the seat is tilted more than 20 degrees the elevating seat will not elevate. Also, if the seat is elevated more than .75 inches, the seat will not tilt.

The MIV Elevating Seat Toggle and the MIV TAC are to be used in conjunction with the **Invacare Model MCC-MKIV Motor Controller , Joystick and options. FDA granted this controller marketing clearance on June 2, 1994, under 510(k) Accession Number K940972.**

**B. Substantial Equivalence**

The Invacare Elevating Seat is substantially equivalent to the Accelerated Rehab Designs, Inc. "E-2000 Power Elevating Seat System" (K992828, 2/3/2000).

**PERFORMANCE DATA**

The Invacare Elevating Seat 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."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2125

Re: K013516
Trade Name: Invacare Elevating Seat Option ESS6
Regulation Number: 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: October 19, 2001
Received: October 23, 2001

Dear Ms. Farrow:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

for Mark N Milhern

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):** *TBD*

**Device Name:** *Invacare Elevating Seat Option*

**Indications For Use:**

*The intended function and use of the Invacare Elevating Seat is to provide powered elevation of the wheelchair seat and user in order to assist the user with daily activities, transfers and general accessibility..*

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** _____ **OR** **Over-The-Counter Use** _____
**(Per 21 CFR 801.109)**

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013576

**(Optional Format 1-2-96)**