

OCT 5 1998

K982064

**510(k) SUMMARY**

**Invacare Corporation's  
Models Action Storm Ranger II and Power 9000 Front Wheel Drive Power  
Wheelchairs**

**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: Edward A. Kroll  
Director, TQM and Regulatory Affairs

Date Prepared: June 10, 1998

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

Models Action Storm Ranger II and Action Storm Power 9000 Power  
Wheelchairs

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

**Common or Usual Name**

Power Wheelchair

**Classification Name**

Wheelchair, Powered

### **Predicate Devices**

The Models Ranger II and Power 9000 Front Wheel Drive power wheelchairs are substantially equivalent to Permobil's Chairman (K960951, April 4, 1997) Front Wheel Drive Power Wheelchair and Invacare Power 9000 (K900565, February 2, 1990) power wheelchairs. The wheelchairs are controlled using the Invacare Model MCC-MKIV RII Motor Controller and Joystick. This controller was granted marketing clearance by FDA on June 2, 1994, under 510(k) Accession Number K940972.

### **Intended Use**

The intended use of the Invacare Action Storm and Ranger II Front Wheel Drive Power Wheelchairs is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

### **Technological Characteristics and Substantial Equivalence**

#### **A. Device Description**

The Invacare Models Ranger II and Power 9000 front wheel drive power wheelchairs are battery powered, motor driven devices with the intended function and use of providing mobility to those persons limited to a sitting position that have the capability of operating a power wheelchair. They are non rigid, or "folding" type, front wheel drive power wheelchairs.

The wheelchairs are controlled using the Invacare Model MCC-MKIV RII Motor Controller and Joystick. They are powered by two Size 22NF 12 VDC batteries. Access to the batteries is gained from underneath the chair. The chairs will travel approximately 17 to 22 miles between charges, depending on use.

The wheelchairs consist of two basic sub-sections. These are the base section of the wheelchair, and the seating section of the wheelchair. Both are of welded steel construction. The base section includes the base frame, front drive wheels and axles, rear pivoting casters, motor/gearbox drive mechanism and batteries. The motor/gearbox location is adjustable, relative to the upper seating frame. This adjustment is used to compensate for weight and balance shift, which are both user dependent.

The seating, or upper section of the wheelchair, includes the seating upholstery, front foot rests, side arm rests, and joystick operating control. Seating sizes range from 14" wide to 20" wide, depending on user needs. The wheelchair motor controller is mounted to the side arm and under the backrest of the seat. The upholstery material is fabricated from either U240 Nylon, or reinforced vinyl, depending upon the user's preference. Both of these materials meet California 117 and Boston Fire Department BFD-1 specifications for fire retardancy.

### **B. Substantial Equivalence**

Products which are substantially equivalent to these devices are Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997) and Invacare Corporations' Power 9000 (K900565, February 2, 1990) power wheelchairs.

Each of these products are battery powered, motor driven powered wheelchairs with the same intended function and use which is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair. Similarities include large wheels with attached motor/gearbox drive mechanisms, smaller pivoting casters for turning, and joystick operated motor controllers to engage system motion and steer the wheelchair. 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**

As required by FDA's July 26, 1995, draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three- Wheeled Vehicles", the Invacare Action Storm and Ranger II Front Wheel Drive Power Wheelchairs were tested in accordance with ISO EMC Draft Standard 7176-14 (Titled "Draft ISO EMC Group Proposal: Electromagnetic Compatibility Addition" And Dated April 3, 1995) for powered wheelchairs and motorized scooters. In all instances, the Invacare Action Storm and Ranger II Front Wheel Drive Power Wheelchairs met the required performance criteria and functioned as intended.

15'



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 5 1998

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

Re: K982064  
Action Storm Ranger II, Action Storm Power 9000  
Regulatory Class: II  
Product Code: ITI  
Dated: August 25, 1998  
Received: September 11, 1998

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 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.

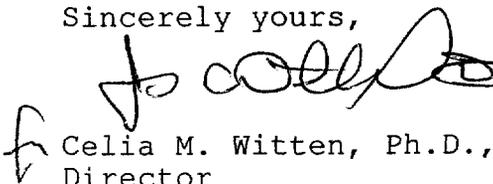
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Edward A. Kroll

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,



f 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:** *Invacare Models Ranger II and Power 9000 Front Wheel Drive Power Wheelchair*

**Indications For Use:**

*To provide mobility to persons limited to a seated position.*

**(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)

\_\_\_\_\_  
**(Division Sign-Off)**  
**Division of General Restorative Devices**  
**510(k) Number**                     12982064