JUN 25 1999

K991168

510(k) SUMMARY

Invacare Corporation's
Model Arrow Front Wheel Drive Power Wheelchair

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: April 5, 1999

Name of Device and Name/Address of Sponsor

Models Arrow Front Wheel Drive Power Wheelchair

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

Invacare Corporations' Action Storm Ranger II and Action Storm Power 9000 Front Wheel Drive Power Wheelchairs (K982064 , October 5, 1998) and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).

Intended Use

The intended use of the Invacare Arrow Front Wheel Drive Power Wheelchair 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 Model Arrow Front Wheel Drive (FWD) Power Wheelchair is a battery powered, motor driven device 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. It is a rigid or " non- folding" type power wheelchair, with front wheel drive capability.

Front wheel drive means that the drive motors are connected directly to the front wheels of the wheelchair, as opposed to a rear wheel drive chair which connects the drive motors to the rear wheels. Mounting the drive wheels on the front of the wheelchair, results in a chair that is easier to maneuver than the traditional rear wheel drive wheelchair. Because the center line of the pivoting casters is now behind the user, the user experiences a more natural feel when turning the wheelchair.

B. Substantial Equivalence

The Invacare Model Arrow FWD Power Wheelchair is substantially equivalent to other devices of comparable type that are currently being legally marketed within the United States. The comparable devices include those manufactured by Invacare as well as its' competitors.

Products which are substantially equivalent to these devices are **Invacare Corporations' Action Storm Ranger II and Action Storm Power 9000 Front Wheel Drive Power Wheelchairs (K982064 , October 5, 1998) and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).**

Each of these products are battery powered, motor driven, front wheel drive 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 Arrow Front Wheel Drive Power Wheelchair was 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 Arrow Front Wheel Drive Power Wheelchair met the required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1999

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

Re: K991168
Arrow Front Wheel Drive (FWD) Power Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: April 5, 1999
Received: April 7, 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 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

510(k) Number (if known): *TBD* K991168

Device Name: *Invacare Model Arrow Front Wheel Drive (FWD) Power Wheelchair*

Indications For Use:

Its intended use is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

(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** X
(Per 21 CFR 801.109)

(Division Sign-Off) **(Optional Format 1-2-96)**
Division of General Restorative Devices K991168
510(k) Number