JAN 8 1999

K984447

510(k) SUMMARY

Invacare Corporation's
Model Action AT II Manual Wheelchair

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: December 11, 1998

Name of Device and Name/Address of Sponsor

Model Action AT II Manual Wheelchair

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 36-4558

Common or Usual Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical 89IOR

Predicate Devices

The Invacare Model Action AT II substantially equivalent to the Sunrise Medical/Quickie Design Model **"Quickie TSR"** Manual Wheelchair **(K952641 6/9/95)** and the Invacare Model Action AT Manual Wheelchair **(K941989 6/11/94).**

Intended Use: The intended use of the Model Action AT II Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Technological Characteristics and Substantial Equivalence

A. **Device Description** The Invacare Corporation Model Action AT II is a manually operated, self propelled, manual, mechanical wheelchair. It's intended function and use is to provide mobility to persons who may be restricted to a sitting position. This product may also be used as an attendant propelled patient transport device in a health care environment such as a hospital, nursing home or extended care facility.

The product consists basically of the wheelchair frame, larger rear wheels with handrims for propelling the chair, and smaller front pivoting casters for steering and turning.

The wheelchair frame is constructed from both 1¼" and 1" outside diameter (OD) round, mechanical, steel tubing. The side frames are of welded construction and are secured to the remaining frame members using screws and bolts. This device is a rigid, "non folding" type wheel chair that incorporates a solid seating surface. This type of seat makes the chair easily adaptable to the various types of wheelchair cushions and seating systems currently available in the market.

The Action AT II also includes a "Tilt in Space" feature which allows the seat and back of the wheelchair to be tilted. This feature is used for those patients who require a tilt feature for stability, comfort or head control. It also serves as an attendant aid in those situations where a patient need to be tilted to be fed, or attended to in some fashion. The attendant version of the chair also is available with a stroller type push handle for ease of attendant pushing.

The "Tilt in Space" feature is manually operated and is activated by two release levers located at the rear of the wheelchair. Adjusting the tilt is achieved by squeezing the two release lever handles inward simultaneously. When the levers are squeezed, flexible cables attached to each release lever disengage gear rack segments from independent actuator rods which are notched to match the teeth of the gear segments. Once the desired tilt angle has been obtained, the handles are released and the chair will remain at the angle chosen. The chair has a tilt angle range of 55 degrees.

B. <u>Substantial Equivalence</u>

The Invacare Model Action AT II substantially equivalent to numerous manual, mechanical wheelchairs currently in market place, for which FDA has granted marketing clearance through the 510(k) premarket notification process. More specifically the Invacare Action AT II is substantially equivalent to the Sunrise Medical/Quickie Design Model **"Quickie TSR"** Manual Wheelchair **(K952641 6/9/95)** and the Invacare Model Action AT Manual Wheelchair **(K941989 6/11/94).**

Each of the products is a manually operated, attendant or user propelled, manual mechanical wheelchair with the same intended function and use which is to provide mobility to persons that may be limited to a seated position. All products consist basically of a mechanical frame to support the wheelchair, large rear wheels for propelling the wheelchair, and smaller front pivoting casters for turning and steering. Additionally, each of these wheelchairs incorporates a manually operated "tilt in space" feature for patient comfort and positioning.

Performance Data

The Invacare Action AT II manual wheelchair meets the applicable performance requirements specified in:

- Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/Vol.1-1998 "Requirements and Test Methods for Wheelchairs (Including Scooters)

- DIS ISO 7176 (1992) - Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 1999

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

Re: K984447
Trade Name: Action AT II Manual Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: December 11, 1998
Received: December 14, 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.

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,

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): K984447

Device Name: *Action AT II Manual Wheelchair*

Indications For Use: *To provide mobility to persons limited to a sitting postion.*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K98444