

K012927

SEP 19 2001

510(k) SUMMARY

**Invacare Corporation's
Model M71 Power Wheelchair**

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

Invacare Corporation
One Invacare Way
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Elyria, Ohio 44036
Phone: (440) 329-6000
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Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: August 30, 2001

Name of Device and Name/Address of Sponsor

Model M71 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 Arrow Front Wheel Drive Power Wheelchairs (K991168 June 25, 1999), Invacare Corporations' Ranger II M6 Power Wheelchair (K002157, August 25, 2000), and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).

Intended Use

The intended use of the Invacare Model M71 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 M71 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 mid wheel drive capability.

The wheelchair frame is of rigid or non-folding type design. The wheelchair frame is of rigid or non-folding type design. The frame consists predominately of round 1 ¼ " diameter x .07 wall, steel tubing. The frame is of welded construction. The chair can be disassembled into 6 pieces without the use of tools for transport in vehicles that are not equipped with wheel chair lifts and ramps. To easy re-assembly, the mating parts are color-coded or labeled at the joints. Painted shrouds are used to conceal the wheelchair frame, motors and controller.

The wheelchair is designed with front wheel, walking beam type suspension. That is, the front swivel casters are mounted to two separate front extension frame members, and are thus, independent of each other. Each extension frame member pivots independently in a vertical plane about a horizontal axis. This allows the chair to better negotiate small obstacles such as curbs, or ramps, from a complete stop. The rear casters pivot as well, and also serve as wheelchair anti-tippers.

The Invacare M71 wheelchair incorporates a direct, drive, which includes two separate right angle gear motors. Because it is a direct drive system, there are no belts, pulleys, chains, sprockets or the like, to periodically adjust or maintain. Both gearboxes are sealed and maintenance free.

The Invacare M71 wheelchair is powered by two 12 volt, U-1 deep cycle gel cell batteries. The operating range, between battery re-charging is approximately 12 miles. Range will vary with battery condition, surface terrain and operator weight. The On Board Charger is standard.

B. Substantial Equivalence

The Invacare Model M71 Power Wheelchair is substantially equivalent to Invacare Corporations' Action Arrow K991168, June 25, 1999), Invacare Corporations' Ranger II M6 Power Wheelchair (K002157, August 25, 2000), and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).

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 M71 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 M71 Power Wheelchair met the required performance criteria and functioned as intended.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2028

Re: K012927

Trade/Device Name: M71 Power Wheelchair
Regulation Number: 890.3860
Regulation Name: Wheelchair, Powered
Regulatory Class: II
Product Code: ITI
Dated: August 30, 2001
Received: August 31, 2001

Dear Ms. Farrow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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,



 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): ~~FBI~~ K012927

Device Name: Invacare M71 Power Wheelchair

Indications For Use:

The intended use of the Invacare M71 Power Wheelchair 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)



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

Prescription Use _____
(Per 21 CFR 801.109)

Over-The-Counter Use _____

510(k) Number K012927