

13.0 510(k) SUMMARY OF SAFETY AND EFFICACY

DEC - 2 1997

Submitter: Quickie Designs, Inc.
 2842 Business Park Ave.
 Fresno, CA 93727
 Phone (209) 292-2171
 Fax (209) 292-2741

K972230

Date: Rebecca Andersen
 June 9, 1997

Name(s) of the device(s):

P90 Power Wheelchair Series

Identification of predicate device(s):

- 1) Metro power by Everest & Jennings
- 2) Action Power 9000 by Invacare Corporation
- 3) Action Power 9000 Storm Series by Invacare Corporation

Description of the device:

Quickie P90 Power Wheelchairs consists of typical components found on most wheelchairs, such as push handles, armrests, backrest, seat frame, cushion, footrest and casters. Accessories include items such as positioning belts, backpacks, seat pouches, oxygen tank holders, IV poles, etc. As motorized wheelchairs, they also contain controllers, joysticks, motors, brakes, drive wheels and batteries. Many of these components are available in a range of sizes, shapes, angles, forms, materials or coverings. These variations allow the chairs to be configured to meet the specific desires and needs of the user. Refer to section 7 for a component diagram of a Quickie P90 chair figure 1; for nominal dimensions see figure 2.

Intended use:

Quickie powered wheelchairs empower physically challenged persons by providing a means of mobility. This includes conditions in all ages such as :

Arthritis	Tetraplegic	Multiple Sclerosis
Amputee	Quadriplegic	Polio
Paraplegic	Spina Bifida	Geriatric conditions
Cerebral Palsy	Head Injury or Trauma	And other immobiliz-
Hemiplegic	Muscular Dystrophy	ing or debilitating
		condition

Comparison of device characteristics to predicate(s):

This device has similar technological characteristics as the predicated devices. They all use steel and aluminum in their frame and components, and standard foams and covers for the slings and backs. Microprocessors are typically used with a programmable controller, and the rider controls the chair using a joystick or other equivalent command mode. Motors use permanent magnets, employing 24 volt D.C., with rechargeable deep cycle batteries for an energy source. The operating speeds and maneuverability are equivalent, and recommended for indoor or light outdoor use. The standard accessories and components are common to all power wheel chair lines.

Testing:

This device has been tested to both ISO7176 and ANSI/RESNA Wheelchair Standards. They include:

- Static Stability
- Dynamic Stability
- Effectiveness of Brakes
- Energy consumption
- Overall Dimensions
- Maximum Speed acceleration and retardation
- Static Impact
- Fatigue Strength
- Climatic Test
- Obstacle Climbing Ability
- Testing of Power and Control System
- EMC Testing

We have also tested to the Proposed :

Addition to ANSI/RESNA W/C 14 Electromagnetic Compatibility Requirements for powered Wheelchairs and Motorized Scooters Version 1.5 Dated 1/11/94

ISO EMC Draft Standard 7176-14 Refined Draft ISO EMC Group Proposal Electromagnetic Compatibility Addition Dated 4/3/95 Regarding Electromagnetic Compatibility Requirements for Powered Wheelchairs and Motorized Scooters.

Safety:

An analysis of complaints against Quickie power chairs was completed and charted. This analysis was supported by a literature search which was conducted by a third party to determine the number of complaints, MDR's and recalls that have been reported to the FDA concerning wheelchairs in general. This information was summarized, and presented in a Management Review report dated 2/20/97. The data and charts are included as Attachment 13 - A. The analysis demonstrated common issues across all manufacturers product lines, and varying levels approximately comparable to relative market share. Quickie has concluded that there are no use issues exclusive to Quickie chairs at this time.

Efficacy

Articles are being provided on the use and efficacy of power wheelchairs.

- 1) "A Question of Power", Team Rehab Report, by Robbie B. Leonard, MS, PT, pp. 22-23, May 1992
- 2) "Preventing occupied wheelchairs from falling down stairs", Journal of Rehabilitation Research, by R. Lee Kirby, MD. And Angus D. McLean, Dip Eng Bsc., PP 27 - 32, Vol. 27 No. 1, Winter 1990.
- 3) "Powered Mobility and Its Implications", JRRD Clinical Supplement, by C. Gerald Warren, pp. 74 - 85, Technical Paper.

510(k) number:

Not assigned at the writing of this summary

Conclusion:

The Quickie P90 Power Wheelchair is substantially equivalent to the predicated devices listed in this 510(k) and the technology and construction of the P90 does not raise any new issues of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Rebecca Andersen
Vice President, Quality and Regulatory Affairs
Sunrise Medical
Mobility Products Division
7477 A East Dry Creek Parkway
Longmont, Colorado 80503

DEC - 2 1997

Re: K972230
P120 Series
Regulatory Class: II
Product Code: ITI
Dated: September 4, 1997
Received: September 9, 1997

Dear Ms. Andersen:

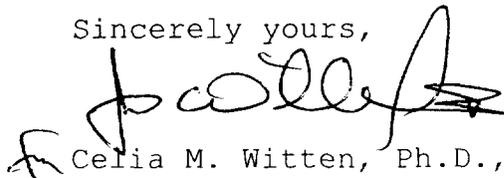
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 pre-market 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): K972230

Device Name: Quickie P90 (New Home P-120)

Indications For Use:

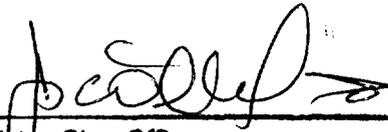
Please amend Section 12.2, Indications for Use as found on Page 58 to read:

Quickie powered wheelchairs empower physically challenged persons by providing a means of mobility. This included conditions in all ages such as:

- | | |
|---------------------------|---|
| Arthritis | Head Injury or Trauma |
| Amputee | Muscular Dystrophy |
| Paraplegic | Multiple Sclerosis |
| Cerebral Palsy | Polio |
| Hemiplegic | Geriatric Conditions |
| Tetaplegic (Quadraplegic) | And other immobilizing or debilitating conditions |
| Spina Bifida | |

(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 Devices
 510(k) Number K972230

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)