K982336

AUG 21 1998

510(k) SUMMARY

Invacare Corporation
Kuschall Design AG
K3/K4 series of manual 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) 329-6595
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: June 26, 1998

Name of Device and Name/Address of Sponsor

Kuschall Design K3/K4 series of manual wheelchairs

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

Name and Address of Manufacturer

Kuschall Design AG
Ringstrasse 15
4123 Allschwill Switzerland
Phone: 011-41-61-481-5666
Facsimile: 011-41-61-481-5240

Common or Usual Name

Manual Wheelchair

Classification Name

Wheelchair, Mechanical

Predicate Devices
The Kuschall Design K3/K4 series of manual wheelchairs are substantially equivalent to the Invacare Action Pro and Pro T Manual Wheelchairs (K914553, 10/9/91).

Intended Use
The intended use of Kuschall Design K3/K4 series of manual wheelchairs is to provide mobility to persons limited to a sitting position.

Technological Characteristics and Substantial Equivalence

A. **Device Description**
The Kuschall Design K3/K4 series of manual wheelchairs are lightweight wheelchairs that provide mobility to persons limited to a sitting position. They consist of a rigid, mechanical, aluminum frame and a coated nylon upholstery that meets EN1021-1: Assessment of the Ignitability of Upholstered Furniture. They have larger rear wheels with handrims for pushing and steering. They have smaller front casters for turning and maneuverability. Different front casters are available. The K3 has 3 wheels, 2 large rear wheels and 1 front caster. The K4 has 4 wheels, 2 large rear wheels and 2 front casters.

The Kuschall Design K3/K4 series is available in various seat width's, depths, and heights and has an adjustable seat angle and tip stability. The camber is also adjustable to various increments.

They are sporty looking chairs with a more high performance feel that the standard version wheelchair. They are intended for the more active user.

B. Substantial Equivalence
The Kuschall Design K3/K4 series of manual wheelchairs are substantially equivalent to the Action Pro and Pro T Manual Wheelchairs (K914553, 10/9/91).

Each of these products are lightweight manual wheelchairs with the intended use of providing mobility to a person limited to a seated position. They are rigid frames with foldable backs and adjustable seat angle, tip stability and camber.

PERFORMANCE DATA
The Kuschall Design K3/K4 series was tested by TUV Product Service to the following standards and met all the requirements:

- DIN EN 12182 (2/96) Manually Propelled Wheelchair Requirements and Test Methods
- DIN ISO 7176 - Part 8 (1992) Wheelchairs - Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- EN 1021-1 Furniture - Assessment of the Ignitability of Upholstered Furniture

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 1998

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

Re: K982336
Kuschall Design K3/K4 Series of Manual Wheelchairs
Regulatory Class: I
Product Code: IOR
Dated: June 26, 1998
Received: July 6, 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,

Mark N Melkerson

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*

Device Name: *Kuschall Design K3/K4 series of manual wheelchairs*

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)

Mark N Melkerson

for CDRH (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982336

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)