MAY 1 2 2004

510(K) SUMMARY
KUSCHALL CHAMPION, COMPACT AND ULTRA-LIGHT

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is: _____

Date: April 23, 2004

Submitted by: Kuschall Design AG
Ringstrasse 15
Allschwill, Switzerland CH-4123

Contact Telephone: 440-329-6356
Fax: 440-326-3607

Contact Person: Carroll L. Martin, Regulatory Affairs

Trade Name: Kuschall Champion, Kuschall Compact and Kuschall Ultra-Light

Common Name: Manual wheelchair

Classification Name: Wheelchair, mechanical per 21 CFR section 890.3850

Legally Marketed Predicate Device(s): Invacare Action AF-1 (now known as "The Spyder"), K000174, February 18, 2000
Invacare MVP, K914553, October 28, 1991

Device Description: The Kuschall Champion, Compact and Ultra-Light are manually operated, user-propelled mechanical wheelchairs. Their intended use is to provide mobility to persons restricted to a seated position.

Each wheelchair consists primarily of a metal frame that is constructed of round and oval aluminum tubing that is welded, large rear wheels with hand rims for propelling the chair and smaller front pivoting casters for steering and turning. The Kuschall Champion is also available with a carbon fiber frame. The products are designed to be lightweight, everyday wheelchairs for both indoor and outdoor use. They are all folding, non-rigid wheelchairs.

Intended Use: The intended use of the Kuschall Champion, Compact and Ultra-Light manual wheelchairs is to provide mobility to persons restricted to a seated position.

Substantial Equivalence: Product that is substantially equivalent to the Kuschall Champion is the Invacare Action AF-1, (K000174, February 18, 2000) now known as "The Spyder". These products are both manually operated, user propelled mechanical wheelchairs with the intended use of providing

mobility to persons restricted to a seated position. Both products consist basically of a metal frame, larger rear wheels with hand rims for propelling the wheelchair and smaller front pivoting casters for steering and turning.

The Kuschall Champion folds using two connecting arms that are hinged together in the center of the wheelchair, but are also hinged at the side frames. As such, the chair essentially folds "horizontally", the same manner in which the Invacare AF-1 folds, as opposed to the vertical folding of a cross brace wheelchair.

The folding mechanism allows the backrest and the seat to be folded simultaneously. The frame remains closed by the use of a Velcro strap while transferring the chair into the car.

The Kuschall Compact and Ultra-Light are similar to the Invacare MVP (K914553, October 28, 1991) in that all three wheelchairs are manually-operated, user propelled mechanical wheelchairs with the intended use of providing mobility to persons restricted to a seated position. All three devices consist basically of a metal frame, larger rear wheels with hand rims for propelling the wheelchair and smaller front pivoting casters for steering and turning.

The Kuschall Compact, Ultra-Light and Invacare MVP all have the ability to fold and fold in the traditional "vertical" manner. The folding mechanism is of the "X" cross brace design whereby the lower frames cross, or form an "X" in the center and are hinged at a single pivot point for folding. These chairs fold by collapsing "vertically" about the center pivot point

Additional similarities and differences are listed in the substantial equivalence matrices for each compared product. None of the differences alter the intended function and use of the devices nor do they raise any new questions of safety and effectiveness.

Software: No software is associated with these devices.

Performance Data: The following performance standards were used during the development of the Kuschall Champion, Compact and Ultra-Light and it has been determined that each wheelchair met the applicable specified requirements:

- EN 12183: The Swedish Handicap Institute's Specification of Requirements for Manually Propelled Wheelchairs
- prEN 12182: Technical Aids for Disabled Persons – General Requirements and Test Methods
- EN 1041: Information Supplied by the Manufacturer with Medical Devices
- ISO 7176-1: Wheelchairs – Part 1: Determination of Static Stability
- ISO 7176-3: Wheelchairs – Part 3: Determination of Efficiency of Brakes
- ISO 7176-8: Wheelchairs – Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- ISO 7176-11: Wheelchairs – Part 11: Test Dummies
- ISO 7176-13: Wheelchairs – Part 13: Determination of Coefficient of Friction of Test Surfaces

- ISO 7176-15: Wheelchairs – Part 15: Requirements for Information Disclosure, Documentation and Labeling
- ISO 7176-16: Wheelchairs – Part 16: Resistance to Ignition of Upholstered Parts – Requirements and Test Methods
- ISO 8191-1: Furniture – Part 1: Assessment of The Ignitability of Upholstered Furniture; Ignition Source: Smoldering Cigarette
- ISO 8191-2: Furniture – Part 2: Assessment of Ignitability of Upholstered Furniture; Ignition Source: Match-Flame Equivalent
- ISO 9999: Technical Aids for Disabled Persons - Classification
- ISO 6440: Wheelchairs – Nomenclature Terms and Definitions
- CA Bulletin 117 - Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 2 2004

Carroll L. Martin
Regulatory Affairs
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K041072
Trade/Device Names: Kuschall Champion, Kuschall Compact and Kuschall Ultra-light
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: April 23, 2004
Received: April 26, 2004

Dear Mr. Martin:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

for Mark N. Melkerson

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

Indications for Use

510(k) Number (if known):

Device Name: Kuschall Champion
Kuschall Compact
Kuschall Ultra-light

Indications for Use:

The Kuschall Champion, Compact and Ultra-light are mechanical wheelchairs intended to provide mobility to persons restricted to a sitting position.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓
(21 CFR 807 Subpart C)

(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

510(k) Number K041072