DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 28, 2016

Invacare Corporation
Elijah Wreh
Regulatory Affairs Manager (pre-market)
One Invacare Way
Elyria, Ohio 44035

Re: K162696
Trade/Device Name: Kuschall Advance Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 26, 2016
Received: September 27, 2016

Dear Elijah Wreh:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162696

Device Name
Küschall Advance Manual Wheelchair

Indications for Use *(Describe)*
The device is indicated to provide mobility to persons limited to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

SUBMITTER: Invacare Corporation
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Regulatory Affairs Manager (Pre-Market)

MANUFACTURER: KUSCHALL AG
Benkenstrasse 260
Witterswil Solothurn
SWITZERLAND 4108

Date Prepared: December 19, 2016

DEVICE
Name of Device: Küschall Advance Manual Wheelchair
Common or Usual Name: Wheelchair, Mechanical
Classification Name: Mechanical Wheelchair 21 CFR §890.3850

Regulatory Class: I

Product Code: IOR

PREDICATE DEVICE: Küschall Design K3/K4 Series Manual Wheelchair (K982336)

No reference devices were used in this submission

DEVICE DESCRIPTION

The subject Küschall Advance Manual Wheelchair is available in a number of seat width, depth and height option. The subject device is a manual or attendant operated wheelchair that is indicated to provide mobility to persons limited to a sitting position with a weight capacity of 276 lbs. The standard components of the subject device include a complete rear wheels (hand rims and tires), front castors, tube style, footrest, carbon cloth guards, fold down and locking backrest, wheel locks and quick release axles. The carbon seat pan has a central Velcro band that is used for fixation. There is no prior submission for the subject device.

INDICATIONS FOR USE

The device is indicated to provide mobility to persons limited to a sitting position.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The device comparison showed that the subject device is substantially equivalent to the previously cleared Küschall K3-K4 Series Manual Wheelchair (K982336) in regards to intended use, design, materials, and operational principles to provide mobility to persons limited to a sitting position.

Design Comparison – Invacare Küschall Advance Manual Wheelchair

Device	**Küschall Advance**	**Küschall Design K3/K4 Series Manual Wheelchair**
510(k) Number	Subject Device Pending Submission (K162696)	Predicate Device (K982336)
Indications for Use	The device is indicated to provide mobility to persons limited to a sitting position.	Provide mobility to persons limited to a sitting position.
Design		
Weight Limit	276 lbs.	265 lbs.
Seat Width	13.5”-18”	14”-18”
Seat Depth	14”-20.5”	14”-18”
Back Style	Angle adjustable and foldable	Angle adjustable and foldable
Back Height	10.5”-19”	10.5”-19”
Back Angle	78°-94°	70°-90°
Number of Wheels	4	3 or 4
Rear Wheel Sizes	22”-26”	24”
Device Weight	19.4 lbs. 13.7 lbs. (without wheels)	21 lbs.

PERFORMANCE DATA

Non-Clinical Test

The Küschall Advance Manual Wheelchair has been evaluated through non-clinical performance testing and is in compliance with the following test standards:

- RESNA WC-1:2009 Section 1: Determination of Static Stability
- RESNA WC-1:2009 Section 3: Determination of Effectiveness of Brakes
- RESNA WC-1:2009 Section 5: Determination of Dimensions, Mass and Maneuvering Space
- RESNA WC-1:2009 Section 7: Method of Measurement of Seating and Wheel Dimensions
- RESNA WC-1:2009 Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- RESNA WC-1:2009 Section 11: Test Dummies
- RESNA WC-1:2009 Section 13: Determination of Coefficient of Friction of Test Surfaces
- RESNA WC-1:2009 Section 15: Requirements for Information Disclosure, Documentation and Labeling
- RESNA WC-1:2009 Section 16: Resistance to Ignition of Upholstered Parts
- CAL 117:2013 Section 1: Flammability testing

Testing demonstrated that the subject Küschall Advance Manual Wheelchair is substantially equivalent to the marketed predicate device identified throughout this 510(k) submission.

Biocompatibility Testing

The biocompatibility evaluation for the subject Küschall Advance Manual Wheelchair was conducted in accordance with the FDA Blue Book Memorandum #G95 − 1 "Use of International Standard ISO − 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993 − 1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- AAMI / ANSI / ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for *in vitro* Cytotoxicity
- AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Irritation

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

CONCLUSIONS

The subject device has the same intended use and similar technological characteristics as the predicate device. The non-clinical laboratory data support the substantial equivalence of the subject Küschall Advance Manual Wheelchair and demonstrate that the subject device should perform as intended in the specified use conditions. Therefore, the Küschall Advance Manual Wheelchair is substantially equivalent to the predicate device identified throughout this submission