July 1, 2019

Broda Seating (Broda LP)
Jeremy Ballard
Product Manager
560 Bingemans Centre Drive
Kitchener, ON, N2B3X9 CA

Re: K190550
Trade/Device Name: IKON 40 Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: March 28, 2019
Received: March 28, 2019

Dear Jeremy Ballard:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek Pinto, Ph.D.
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190550

Device Name
IKON 40 Manual Wheelchair

Indications for Use *(Describe)*
The standard IKON 40 is a manual wheelchair device that is intended to be used to provide mobility to persons ages 12 and over (adolescents and adults) with a weight capacity of 300 lbs. The device is to be used as a means of mobility for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared (revised): June 28,2019

K190550

Submitter:

Broda Seating (Broda LP)

560 Bingemans Centre Drive

Kitchener, ON, N2B3X9

Registration Number 8043392

Phone: 844-552-7632

Fax: 844-442-7632

Device:

Device Trade Name: IKON 40 Manual Wheelchair

Common or Usual Name: Folding Ultra-Lightweight, Manual Wheelchair

Classification Name: Mechanical Wheelchair 21 CFR §890.3850

Regulatory Class: I

Product Code IOR: Wheelchair, mechanical

Predicate Device:

MyOn HC™ Manual Wheelchair (K152536); manufactured by Invacare®

(1525712)

Device Description:

Technical Specifications (* Standard Configuration):

The IKON 40 is a foldable, ultra-lightweight and fully adjustable manual wheelchair.

Specification	IKON 40	
Cross bar	*1 x 1	2 x 1
Seat widths	16", *18"	20", 22"
Seat depths	16"- 22" Adjustable	16"- 22" Adjustable
Seat height	14”, 15”, 16”, 17”, 18", 19” Adjustable	14”, 15”, 16”, 17”, 18", 19” Adjustable
Max user weight	300 lbs.	300 lbs.
Chair length	40"	40"
Chair width	26"	26"
Length (no legrests)	30"	30"
Folded height	34.5"	34.5"
Folded width	13.5"	13.5"
Total weight (Including legrests, armrests and anti-tippers)	34 lbs.	34 lbs.
Front seat height	16"	16"
Backrest height	16.5"	16.5"
Legrests	*Swing Away Elevating	Swing Away Elevating
Legrest range	13.5"- 19" Adjustable	13.5"- 19" Adjustable
Legrest angle (°)	70°	70°
Footrests	Flip Up and Angle Adjustable	Flip Up and Angle Adjustable
Armrests	*Flip Back Adjustable Height Fixed Non-Adjustable	*Flip Back Adjustable Height Fixed Non-Adjustable
Armrest height range	9"- 11" Adjustable	9"- 11" Adjustable
Rear wheel	*22", 24” Spoke 22”, 24” Composite Mag	*22", 24” Spoke 22”, 24” Composite Mag
Front wheel	5”, 6”, *7", 8” Castors	5”, 6”, *7", 8” Castors

Indications for Use:

The standard IKON 40 is a manual wheelchair device that is intended to be used to provide mobility to persons ages 12 and over (adolescents and adults) with a weight capacity of 300 lbs. The device is to be used as a means of mobility for persons limited to a sitting position.

Technological Characteristics Comparison to the Predicate Device:

The following device characteristics comparison demonstrates that the IKON 40 is substantially equivalent in design, construction, operational uses and functionality for persons limited to a sitting position as the previously cleared MyOn HC™ Manual Wheelchair (K152536).

Characteristics	IKON 40	MyOn HC™ (K152536)
Indications for Use (IFU)	The IKON 40 is a manual wheelchair device that is intended to be used to provide mobility to persons ages 12 and over (adolescents and adults) with a weight capacity of 300 lbs. The device is to be used as a means of mobility for persons limited to a sitting position.	The MyOn HC™ Manual Wheelchair is intended to provide mobility to persons over 12 years of age (adolescents and adults) with a weight capacity of 220 & 290 lbs. depending on the seat width. The device is indicated to provide mobility to persons restricted to a sitting position.
Cross brace bars	1 x 1 Aluminum Folding Frame	1 x 1 Aluminum Folding Frame 2 x 1 Aluminum Folding Frame
Folding Method	Collapsible Cross-Brace	Collapsible Cross-Brace
Warranty	Lifetime on Frame	Lifetime on Frame
Seat widths	16", 18", 20", 22"	15", 16", 17", 18",19", 20", 22", 24"
Seat depths	16"- 22" Adjustable	16"- 20" Adjustable
Max user weight	300 lbs. (1 x 1) 300 lbs. (2 x 1)	275 lbs. (1 x 1) 350 lbs. (2 x 1)
Wheelchair weight (Including legrests, armrests and anti-tippers)	34 lbs.	31 lbs.
Seat height	14”, 15”, 16”, 17”, 18", 19” Adjustable	14", 15", 16", 17", 18",19", 20" Adjustable
Legrests	Swing Away Elevating	Swing Away Elevating
Legrest range	13.5"- 19" Adjustable	13.25"- 18.25" Adjustable
Legrest angle (°)	70°	70°, 80°, 90°
Footrests	Flip Up and Angle Adjustable	Flip Up and Angle Adjustable
Armrests	Flip Back Adjustable Height Fixed Non-Adjustable	Flip Back Adjustable Height T Arm Adjustable Height
Armrest height range	9"- 11" Adjustable	9"- 11" Adjustable
Rear wheel	22", 24” Spoke 22”, 24” Composite Mag	24", 25", 26" - Spoke 20", 22", 24" - Composite Mag 20", 24", 25", 26” - Performance
Front wheel	5”, 6”, 7", 8” Castors	5", 6", 8" Castors
Anti-tippers	Yes, Optional	Yes, Optional
Standards – Strength, Stability and Durability	ANSI / RESNA Wheelchair Standard Vol. 1 Section 1,3,5,7,8,15 &16	ANSI / RESNA Wheelchair Standard Vol. 1 Section 1,3,5,7,8,15 &16
Standards – FR	CAL 117 / ISO 8191	CAL 117 / ISO 8191

Performance Testing Data:

Non-Clinical Testing:

Testing was performed by a non-clinical laboratory on the IKON 40 to determine substantial equivalence:

- ANSI / RESNA - ISO 7176-1:2014 Wheelchairs – Section 1: Determination of static stability
- ANSI / RESNA - ISO 7176-3:2012 Wheelchairs – Section 3: Determination of effectiveness of brakes
- ANSI / RESNA - ISO 7176-5:2008 Wheelchairs – Section 5: Determination of dimensions, mass and maneuvering space
- ANSI / RESNA - ISO 7176-7:1998 Wheelchairs — Section 7: Measurement of seating and wheel dimensions
- ANSI / RESNA - ISO 7176-8:2014 Wheelchairs – Section 8: Requirements and test methods for static, impact and fatigue strengths
- ANSI / RESNA - ISO 7176-11 Wheelchairs- Section 11: Test Dummies
- ANSI / RESNA – ISO 7176-13 Wheelchairs- Section 13: Determination of coefficient of friction
- ANSI / RESNA - ISO 7176-15:1996 Wheelchairs — Section 15: Requirements for information disclosure, documentation and labelling
- ANSI / RESNA WC/Volume 1 – 2009, Section16: Resistance to Ignition of Upholstered Parts
- CAL117:2013, Section 1: Flammability Testing
- ISO 8191-1:1987 & 8191-2:1988: Flammability Testing

Animal Study:

Animal testing was not required for this submission

Clinical Testing:

Clinical testing was not required for this submission

Conclusions:

The IKON 40, this 510(k) subject device, has the same intended use, safety and similar technological characteristics as the predicate device, the MyOn HC™. Non-clinical laboratory test results support the safety of the subject device and demonstrate the IKON 40 should perform as intended in the specified use conditions. Broda has determined that therefore, the IKON 40 Manual Wheelchair is substantially equivalent to the predicate device, MyOn HC™, identified above throughout this document.