



Food and Drug Administration
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January 5, 2016

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

Re: K152536

Trade/Device Name: MyOn HC™ Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: December 4, 2015
Received: December 7, 2015

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 and Part 809); 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 and Part 809), 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 yours,

Michael J. Hoffmann -A

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

Indications for Use

510(k) Number (if known)

K152536

Device Name

MyOn HC™ Manual Wheelchair

Indications for Use (Describe)

The MyOn HC™ Manual Wheelchair is intended to provide mobility to persons ages 12 and up (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 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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CONTACT PERSON: Elijah N. Wreh
Regulatory Affairs Manager (Pre-Market)

Date Prepared: January 5, 2016

DEVICE

Name of Device: MyOn HC™ Manual Wheelchair
Common or Usual Name: Wheelchair, mechanical
Classification Name: Mechanical wheelchair 21 CFR §890.3850

Regulatory Class: I

Product Code: IOR: Wheelchair, mechanical

PREDICATE DEVICE: Action Patriot Manual Wheelchair (K930803)
No reference devices were used in this submission.

DEVICE DESCRIPTION

This Traditional [510(k)] submission is being supplied to the U.S. FDA to obtain authorization to market the MyOn HC™ Manual Wheelchair. The MyOn HC™ Manual Wheelchair is a foldable, manually operated fully adjustable lightweight wheelchair. It is indicated to provide mobility to persons which have limitations in mobility. It provides support and mobility to users that are seated in the wheelchair, for limited time up to permanent, full day usage. The design incorporates a horizontal folding mechanism connected to a left & right side frame on which many adjustments can be made to meet the individual user needs. The frame can be either equipped with swing in or swing out, detachable, riggings with an angle of 70°, 80° or 90° or the frame which has a fixed 80° front. It allows 5" of center of gravity (CG) adjustments and stepless backrest angle adjustments from -15° to + 15° which can be achieved whilst the user is seated in the wheelchair. The subject device intended use is to provide mobility to persons ages 12 and up

(adolescents and adults) with a weight capacity of 220 & 290lbs depending on the seat width.

There is no prior submission for the subject device.

The associated accessories include:

- Posture belt
- Tipper aid
- Air pump
- Passive illumination
- Cane holder
- Luggage carrier

INDICATIONS FOR USE

The MyOn HC™ Manual Wheelchair is intended to provide mobility to persons ages 12 and up (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 limited to a sitting position.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The device comparison showed that the subject device is substantially equivalent in intended use, design and operational principles to the previously cleared Action Patriot Manual Wheelchair (K930803). The subject device is substantially equivalent to the predicate device in regards to intended use, design, materials, and operational principles to provide mobility to persons limited to a sitting position.

Design Characteristics Comparison

Design	Action Patriot Manual Wheelchair Predicate Device (K930803)	MyOn HC™ Manual Wheelchair Subject Device Pending Submission
Weight Limit	250lbs	220 & 290lbs*
Cross-brace Configuration	X-design	Folds lengthwise and backwards*
Seat Width	14"-20"	12"-21" *
Seat Depth	16" & 18"	14"-20" * 14"-16" adjustable* 16"-18" adjustable*
Back Style	Fixed or adjustable	Fixed or adjustable
Back Angle Adjustment	-5 to +20 degrees in 5 degree increments	-15 to +15 degrees*
Back Height	15-19", 16", 20"	12"-20"
Arm Types	Flip-back arm rests	Flip-back arm rests, adjustable, desk length
Anti-Tippers	Optional	Optional
Wheel Locks	Push-to-Lock, Pull-to-Lock, Hill Holder	Push-to-Lock, Pull-to-Lock
Rear Wheel Sizes	20", 22", 24"	22"-25" *
Caster Sizes	6", 8"	4"-7" *
Front riggings	60° straight 70° straight	Pivot inwards and outwards 70° straight 80° straight* 90° straight* Elevate 0-80°*

PERFORMANCE DATA

Non-Clinical Test

Non-clinical laboratory testing was performed on the subject MyOn HC™ Manual Wheelchair to determine substantial equivalence. The following testing was performed:

- ANSI / RESNA WC/Volume 2 – 2009, Section 1: Determination of Static Stability
- ANSI / RESNA WC/Volume 1 - 2009, Section 5: Determination of Dimensions, Mass and Maneuvering Space
- ANSI / RESNA WC/Volume 1 - 2009, Section 7: Measurement of Seating and Wheel Dimensions
- ANSI / RESNA WC/Volume 1 - 2009, Section 8: Static, Impact And Fatigue Strengths Tests
- ANSI / RESNA WC/Volume 1 – 2009, Section15: Requirements for Information Disclosure, Documentation and Labeling
- 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

Testing demonstrated that the subject MyOn HC™ Manual Wheelchair is substantially equivalent to the marketed predicate device.

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required for this submission.

CONCLUSIONS

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