K110985

MAY - 3 2011

Icon Adult Manual Wheelchair 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Icon Wheelchairs Inc.
Address	P.O. Box 418 Northampton, MA 01060
Phone number	413-584-4491
Fax number	413-380-0177
Name of contact person	Tom Horton
Date prepared	April 1, 2011
Name of device	
Trade or proprietary name	Icon Adult Manual Wheelchair
Common or usual name	Mechanical Wheelchair
Classification name	Wheelchair Mechanical
Classification panel	Physical Medicine
Regulation	890.3850
duct Code(s)	IOR
Legally marketed device(s) to which equivalence is claimed	Marvel Wheelchair model K082970
Reason for 510(k) submission	The Icon Adult Manual Wheelchair is a new device.
Device description	The Icon Adult Manual Wheelchair is a rigid manual wheelchair, with a centralized modular design. The frame components of the chair are aluminum.
Intended use of the device	The Icon Adult Manual Wheelchair is a mechanical wheelchair intended to provide mobility to persons with disabilities restricted to a seated position.
Indications for use	The Icon Adult Manual Wheelchair is a mechanical wheelchair intended to provide mobility to persons with disabilities restricted to a seated position.

Summary of the technological characteristics of the device compared to the predicate device

Element of Comparison	Icon Adult Manual Wheelchair	Marvel Wheelchair K082970	Comparison to the predicate device
Product Weight	23 lbs	23lbs	No substantive differentiation
Patient Capacity	250	250	No substantive differentiation
Frame Material	Aluminum, titanium, and composite materials	Aluminum and composite materials	No substantive differentiation

Suspension	Air Shock	Air Shock	No substantive differentiation
Seat Width	12-19"	12-18"	The predicate device adjusts in width using a system based on the side-guards, whereas the Icon Adult Manual Wheelchair seat width adjustment system relies on the backrest canes. The Icon system will add to the structure of the backrest, adding strength.
Seat Depth	12-20"	12-20"	No substantive differentiation
Rear Seat to Floor Height	12-21"	15-21"	The Icon Adult Manual Wheelchair system for adjusting the rear seat height is based on a threaded seat-tube system that does not require the use of a "shim-kit" or replacing hardware as is the case in the predicate device.
Front Seat to Floor height	12-21"	16-21"	The Icon Adult Manual Wheelchair system for adjusting the rear seat height is based on a threaded seat-tube system that does not require the use of a "shim-kit" or replacing hardware as is the case in the predicate device.
Seat panel	Carbon Fiber or Composite	Carbon Fiber	No substantive differentiation
Backrest composition	Upholstery or solid (carbon fiber, aluminum or composite)	Carbon Fiber	The Icon Adult Manual Wheelchair will be different from the predicate device in offering a wider choice of materials for the backrest.
Castors	Elastomer tire on aluminum or composite hub, available in sizes from 3-6"	Elastomer tire on aluminum or composite hub, available in sizes from 3-6"	No substantive differentiation – the castors are provided by third party vendors and are common to the wheelchair industry.
Backrest manipulation	Available in fixed or folding.	Available in fixed or folding.	The backrest adjustment system in the Icon Adult Manual Wheelchair will widen the distance between the backrest canes – this will provide additional lateral structural integrity under torsion load.
Rear wheel camber angles	Available from 0-6 degrees	Available from 0-6 degrees	No substantive differentiation

Handrims	Aluminum	Aluminum	No substantive differentiation
Rear Wheels	20, 22, 24, 25, 26	20, 22, 24, 25, 26	No substantive differentiation
Drive	Manual	Manual	No substantive differentiation
Footrest adjustability	Footrest can be adjusted forward, backward, in height, and for angle.	Footrest can be adjusted in height.	The Icon Adult Manual Wheelchair will offer an angle adjustable footrest option, allowing the user to adjust the angle of the footrest, improving comfort and reducing strain on the ligaments of their lower legs – the predicate device does not provide a similar option.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Static Stability	ANSI/RESNA WC/Volume 1-1998, Section 1: Determination of Static Stability	There is no pass/fail criteria for this test – results were as expected
Overall dimensions, mass and manoeuvring space	ANSI/RESNA WC/Volume 1-1998, Section 5: Determination of overall dimensions, mass and manoeuvring space	There is no pass/fail criteria for this test – results were as expected
Static, Impact & Fatigue Strength	ANSI/RESNA WC/Volume 1-1998, Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths	There is no pass/fail criteria for this test – results were as expected
Resistance to Ignition	ANSI/RESNA WC/Volume 1-1998, Section 16: Resistance to Ignition of Upholstered Parts	There is no pass/fail criteria for this test – results were as expected

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

There are no pass/fail criteria for these test – results were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Icon Wheelchair Inc.
% Regulatory Technology Services, LLC.
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

MAY - 3 2011

Re: K110985
Trade/Device Name: Adult Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: April 13, 2011
Received: April 18, 2011

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Icon Adult Manual Wheelchair

Indication for Use: The Icon Adult Manual Wheelchair is a mechanical wheelchair intended to provide mobility to persons with disabilities restricted to a seated position.

Prescription Use____ And/Or Over the Counter Use__X__

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation

Division Sign-Off

Office of Device Evaluation

Evaluation and Safety

510(k)_____

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110985