



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

December 17, 2014

Free Wheelchair Mission
c/o Sharon Rockwell
5582 Chalon Road
Yorba Linda, CA 92886

Re: K141691

Trade/Device Name: GEN_3 Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: November 20, 2014
Received: December 1, 2014

Dear Ms. Rockwell:

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" (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 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,


Felipe Aguel -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

Indications for Use

510(k) Number (if known)

K141691

Device Name

GEN_3 Mechanical Wheelchair

Indications for Use (Describe)

The GEN_3 Mechanical Wheelchair is intended to provide mobility to persons restricted to a seated 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

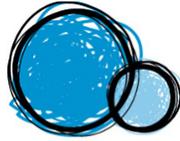
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Free Wheelchair Mission®
TRANSFORMING LIVES THROUGH THE GIFT OF MOBILITY

510(K) SUMMARY (21 CFR 807.92)

GEN_3 MECHANICAL WHEELCHAIR

510(k) Owner: Free Wheelchair Mission
15279 Alton Parkway, Suite 300
Irvine, CA 92618
Tel: 949-273-0858
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Contact Person: Sharon Rockwell
Tel: 714-695-9269
E-mail: srockwell@writeme.com

Date Prepared: June, 2014

Trade Name: GEN_3 Mechanical Wheelchair

Common Name: Mechanical Wheelchair

Classification Name: Mechanical wheelchair per 21 CFR 890.3850, IOR

Predicate Devices: Free Wheelchair Mission GEN_2 Mechanical Wheelchair, K113713

Device Description: The GEN_3 Mechanical Wheelchair is a folding, non-rigid type wheelchair designed for use over rough terrain in developing countries. The wheelchair features adjustable seating, large castor wheels, an extra-thick cushion and adjustable footrests.

Indication for Use: The GEN_3 Mechanical Wheelchair is intended to provide mobility for persons restricted to a seated position.

The Indications for Use for the GEN_3 are identical to those of the GEN_2 Mechanical Wheelchair.

Technological
Characteristics:

The GEN_3 Mechanical Wheelchair is substantially equivalent in design, materials, and intended use to GEN_2 Mechanical Wheelchair as described in the table below:

Feature	GEN_2 (predicate)	GEN_3 (modified device)
Intended Use	To provide mobility to persons restricted to a seated position.	To provide mobility to persons restricted to a seated position.
Frame material	Powder coated steel frame that meets ASTM A 53/A 53M-2005 and JIS G 3444-2004 standards	Powder coated steel frame that meets ASTM A 53/A 53M-2005 and JIS G 3444-2004 standards
Frame widths	13.5-19.5"	14.5-20.5"
Overall widths	29" (medium)	25.6-31.5"
Seat depths	11.5-17"	11.5-17"
Back heights	11.8-19"	11.8-19"
Weight limit	220 lbs	220 lbs
Chair weight	36 lbs (with footrests)	50 lbs (with footrests)
Warranty	No warranty	no Warranty
Armrests	Fixed in place to serve as armrests but not to restrict transfers.	Fixed in place to serve as armrests but not to restrict transfers.
Front end type	Swing-away	Swing-away
Back type	Standard	Standard
Footrest hangers	Not available	Not available
Footplates	Polypropylene, 280 mm adjustable range with angles adjustable to 0, $\pm 7^\circ$, $\pm 14^\circ$, and $\pm 21^\circ$.	Polypropylene, 280 mm adjustable range with angles adjustable to 0, $\pm 7^\circ$, $\pm 14^\circ$, and $\pm 21^\circ$.
Extension tubes	Not available	Not available
Back upholstery	Adjustable to 4 different heights	Adjustable to 4 different heights
Axle plates	Not available	Not available
Wheel sizes	26"	26"
Wheel types	Spoke	Spoke
Tire types	Pneumatic	Pneumatic
Handrims	Powder coated steel	Powder coated steel
Caster sizes	8"	8"
Caster types	Rubber	Rubber
Forks sizes	5"	5"
Wheel locks	Pull to lock	Pull to lock

Feature	GEN_2 (predicate)	GEN_3 (modified device)
Anti tips tubes	No	No
Standards applied	ISO 7176-1, 3, 5, 7, 8, 11, 13, 15, 16	ISO 7176-1, 3, 5, 7, 8, 11, 13, 15, 16
Frame style	Rigid	Non-rigid (folding)
Tubing wall thickness	0.079” throughout	0.079” throughout
Tube properties	ASTM A 53/A 53M-2005 JIS G 3444-2004	ASTM A 53/A 53M-2005 JIS G 3444-2004

The indications for use for the GEN_3 and the GEN_2 mechanical wheelchairs are identical. The size ranges for the GEN_3 in terms of frame width, seat depth, back depths, chair weight and weight limit overlap those of the GEN_2. The GEN_3 is sold in 4 sizes compared to 3 sizes for the GEN_2. All other features are identical with the exception that the frame for the GEN_3 is non-rigid so the chair can be folded. The brakes are identical for both models. The materials used in the welded tube frame, seat, seat back, fire retardant upholstery, foot plates and wheel locks are also identical between the GEN_3 and the GEN_2. The fundamental technology used in the GEN_3 chairs is identical to that of the GEN_2. The information provided supports a substantial equivalence decision based on the repeat pre-clinical testing of the static, impact and fatigue strengths. Any differences in features to the predicate do not affect the performance of the device and do not raise new types of safety or effectiveness questions.

Non-Clinical

Performance Data: Non-clinical testing was repeated per ISO standards to those affected by the change in the frame from a rigid to a non-rigid type (folding chair). The retesting was performed to the following standards:

- 1) ISO 7176-1:1999 Wheelchairs – Part 1: Determination of static stability
- 2) ISO 7176-5:2008 Wheelchairs – Part 5: Determination of dimensions, mass and manoeuvring space
- 3) ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions
- 4) ISO 7176-8:1998 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths

Conclusions:

The non-clinical test results demonstrate the modified GEN_2 Mechanical Wheelchair, called the GEN_3 Mechanical Wheelchair, does not raise any issues regarding safety and effectiveness. The testing supports a determination of substantial equivalence to the GEN_2, Mechanical Wheelchair previously cleared by FDA.