



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

Freedom Designs, Inc.  
Nancy F. Schmidt  
Manager, Customer Relations  
2241 Madera Road  
Simi Valley, CA 93065

October 22, 2015

Re: K151893

Trade/Device Name: P.R.O. CG Manual Wheelchair  
Regulation Number: 21 CFR 890.3850  
Regulation Name: Mechanical Wheelchair  
Regulatory Class: Class I  
Product Code: IOR  
Dated: September 24, 2015  
Received: September 25, 2015

Dear Ms. Schmidt:

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,

**Michael J. Hoffmann -A**

for Carlos 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)  
K151893

Device Name  
P.R.O. CG Manual Wheelchair

Indications for Use (Describe)

The P.R.O. CG® Manual Wheelchair is intended to provide mobility to persons ages 12 and up (adolescents and adults) with a weight capacity of 250lbs.

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 K151893

**SUBMITTER:** Freedom Designs, Inc.  
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Phone: (805) 915-1133

**CONTACT PERSON:** Nancy F. Schmidt  
Manager – Customer Relations/Quality Management  
Representative

**Date Prepared:** October 22, 2015

### DEVICE

**Name of Device:** P.R.O. CG® 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:** Manual Rigid Mobility Wheelchair (K080270)  
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 P.R.O. CG® Manual Wheelchair. The P.R.O. CG® Manual Wheelchair is a rigid, non-folding, manually operated, center of gravity shifting (CG) tilt-in-space wheelchair. The design incorporates a fixed width base frame that is connected to a width and depth adjustable seat frame with struts connected to tilt arcs. This design allows the seat frame to change its position using a CG shifting tilt motion. The shift moves to reposition the seat frame angle from 0° to 50° in a smooth, downward, forward, and backward motion with little change in the overall center of gravity of the frame and the occupant. The device is not marketed with upholstery in the standard or optional configurations. The subject device intended use is to provide mobility to persons ages 12 and up (adolescents and adults) with a weight capacity of 250lbs.

## **INDICATIONS FOR USE**

The P.R.O. CG® Manual Wheelchair is intended to provide mobility to persons ages 12 and up (adolescents and adults) with a weight capacity of 250lbs.

## **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 Manual Rigid Mobility Wheelchair (K080270). 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.

## **PERFORMANCE DATA**

### *Non-Clinical Test*

Non-clinical laboratory testing was performed on the subject P.R.O. CG® Manual Wheelchair to determine substantial equivalence. The following testing was performed:

- ISO International Standard 7176-1: Determination of Static Stability
- ISO International Standard 7176-3 : Determination of Effectiveness of Brakes
- ISO International Standard 7176-5: Determination of Dimensions, Mass and Maneuvering Space
- ISO International Standard 7176-7: Measurement of Seating and Wheel Dimensions
- ISO International Standard 7176-8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- ISO International Standard 7176-11: Test dummies
- ISO International Standard 7176-13: Determination of Coefficient of Friction of Test Surfaces
- ISO International Standard 7176-15: Requirements for Information Disclosure, Documentation and Labeling
- ISO International Standard 7176-19: Wheeled Mobility Device for Use in Motor Vehicles Annex A, C and D
- ANSI/RESNA WC-4: 2012, Section 19: Wheelchairs Used as Seats in Motor Vehicles Annex A, B, C and E
- CAL117:2013, Section 1: Flammability Testing

Testing demonstrated that the subject P.R.O. CG® 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 P.R.O. CG® Manual Wheelchair and demonstrate that the subject device should perform as intended in the specified use conditions. Therefore, the subject P.R.O. CG® Manual Wheelchair is substantially equivalent to the predicate device identified throughout this submission.