

K102910

**510(k) SUMMARY  
PDG Product Design Group  
Luna Manual Wheelchair**

DEC 23 2010

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.**

PDG Product Design Group, Inc.  
Unit 102-366 E. Kent Avenue South  
Vancouver, British Columbia  
Canada V5X 4N6  
Contact Person:

Edward A. Kroll  
President, Spectre Solutions, Inc and  
Representative Consultant for PDG Product Design Group  
5905 Fawn Lane  
Cleveland, Ohio 44141

Date Prepared: September 4, 2010

**Name of Device and Name/Address of Sponsor**

PDG Product Design Group, Inc.  
Unit 102-366 E. Kent Avenue South  
Vancouver, British Columbia  
Canada V5X 4N6  
Contact Person:

**Common or Usual Name**

Wheelchair

**Classification Name**

Wheelchair, Mechanical

**Predicate Device**

Invacare Model 9000 Bariatric Wheelchair (K002317)

**Intended Use**

To provide mobility to persons limited to a sitting position

## **Technological Characteristics and Substantial Equivalence**

### **A. Device Description**

The PDG Model Luna wheelchair is manually operated, self propelled mechanical wheelchair. Its intended function and use is to provide mobility to persons that may be limited to a seated position. It may also be used as attendant propelled transport device in a health care environment such as a hospital, nursing home or extended care facility.

### **B. Substantial Equivalence**

The Luna is substantially equivalent to **Invacare Corporation Model 9000 Bariatric Wheelchair** (Invacare 9000). The Invacare 9000 was granted marketing clearance by FDA on August 25, 2000 under 510(k) Accession Number K002317.

### **Performance Data**

The Luna manual wheelchair is designed to meet the applicable requirements of ISO 7176 – Standard for Manual, Mechanical Wheelchairs.



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

PDG Product Design Group, Inc.  
% Spectre Solutions, Inc.  
Mr. Edward A. Kroll  
President  
5905 Fawn Lane  
Cleveland, Ohio 44141

DEC 23 2010

Re: K102910  
Trade/Device Name: Luna Mechanical Wheelchair  
Regulation Number: 21 CFR 890.3850  
Regulation Name: Mechanical wheelchair  
Regulatory Class: Class I  
Product Code: IOR  
Dated: September 4, 2010  
Received: October 1, 2010

Dear Mr. Kroll:

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.

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

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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" (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 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large initial "M" and "N".

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 (if known): K102910

DEC 23 2010

Device Name: Luna Mechanical Wheelchair

Indications for Use:

To provide mobility to persons limited to a seated position.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

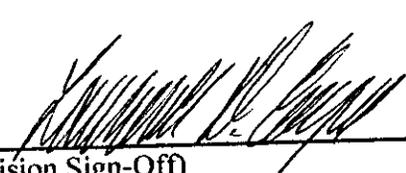
AND/OR

Over-The-Counter Use   
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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