Pride®
Mobility Products Corp.

APR 18 2012

182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990

# Exhibit 1
## 510(k) Summary
## Pride Mobility Products Corporation
## Jazzy Elite 6

**Submitter's Name & Address:**
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-1470

**Contact Person:**
Kimberly Blake

**Date Prepared:**
11/18/2011

**Name of Device and Proprietary Name:**
Jazzy Elite 6

**Common or Usual Name:**
Powered Wheelchair

**Classification Name:**
Physical Medicine / Powered Wheelchair

**Product Code:**
ITI

**Comparison to Predicate Devices:**

The **Jazzy Elite 6** is substantially equivalent to the Pride Mobility Jazzy Frontie (K092961), when comparing performance, maneuverability, stability, and structure. The performance characteristics and the position of the electronics and drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. Refer to Exhibit 7 for verification and validation activities.

The major differences between the **Jazzy Elite 6** and the Jazzy Frontie (K092961) are in the front wheels. The Jazzy Frontie (K092961) has four (4) wheels on the ground while the Jazzy Elite 6 has six (6) wheels on the ground:

- Jazzy Frontie (K092961) utilizes 3" front anti-tip wheels (off of the ground) versus the Jazzy Elite 6 which utilizes 5" front caster wheels (on the ground).

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**Device Description:**

The **Jazzy Elite 6** is a Powered Wheelchair having a digital controller, electrical system, motors, batteries, seating, and frame. The **Jazzy Elite 6** is equipped with electronic regenerative disc brakes, 3A off-board battery charger, removable 12 volt batteries, drive wheels, and front and rear caster wheels.

The **Jazzy Elite 6** is designed with ultimate safety, stability, and performance in mind. The Powered Wheelchair is designed for, but not limited to Pride Mobility Products Corporation, providers/retailers and their consumers.

**Intended Use:**

The intended use of the Pride Mobility Products Corporation device is to provide mobility to persons limited to a seated position that have the capability of operating a Powered Wheelchair.

**Non-Clinical Testing**:

Compliance to applicable Testing Standards is as follows (See 7F for FDA-3654 forms):
RESNA WC Vol.1 2009 - Requirements and Test Methods for Wheelchairs (Including Scooters)
RESNA WC Vol. 2 2009 - Additional Requirements for Wheelchairs (Including Scooters) with Electrical Systems
ANSI/RESNA WC Vol. 2-2008 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.
CAL 117 – Flammability Testing
ISO 10993 –Biocompatibility Testing

**Discussion of Clinical Testing Performed:**
N/A

**Conclusions:**

The **Jazzy Elite 6** Powered Wheelchair has the same intended use and similar technological characteristics as the Jazzy Frontie (K092961), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Jazzy Elite 6** is substantially equivalent to the predicate device, has passed all the necessary testing, and is considered to be safe for user operation.

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

APR 18 2012

Pride Mobility Product Corporation
% Ms. Kimberly Blake
Assistant Manger, Regulatory QA-Regulatory Compliance
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

Re: K113488
Trade/Device Name: Jazzy Elite 6
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 19, 2012
Received: March 19, 2012

Dear Ms. Blake:

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,

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

Enclosure

Pride Mobility Products Corp.

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# Exhibit 3

## Indications for Use

**510(k) Number (if known):** K

**Device Name:** Jazzy Elite 6

**Indications for Use:** The intended use of the Pride Mobility Products Corporation device is to provide mobility to persons limited to a seated position that have the capability of operating a Powered Wheelchair.

**Prescription Use** X **AND / OR** **Over-The-Counter Use** X
**(Part 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

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

510(k) Number K113488