Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

K092961

Exhibit 1

510(k) Summary
Pride Mobility Products Corporation
Jazzy Frontie

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

OCT 23 2009

Contact Person:
Kimberly Blake
Official Correspondent

Date Prepared:
9/15/09

Name of Device and Proprietary Name:
Jazzy Frontie/ Pride Mobility Products Corporation

Common or Usual Name:
Powered Wheelchair

Classification Name:
Physical Medicine / Powered Wheelchair

Product Code:
ITI

Comparison to Predicate Devices:
The **Jazzy Frontie** is substantially equivalent to the Pride Mobility Jet 1 (K001970), 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.

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Device Description:
The **Jazzy Frontie** is a Powered Wheelchair having a digital controller, electrical system, motors, batteries, seating, and frame. The **Jazzy Frontie** is equipped with electronic, regenerative disc brakes, off-board battery charger, removable 12 Volt U1 batteries, front anti-tip wheels, and rear caster wheels.

The **Jazzy Frontie** has a depth adjustable fold flat seat that provides fast, simple adjustment for enhanced, personalized comfort that is removable.

The **Jazzy Frontie** 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 Corp. **Jazzy Frontie** is to provide mobility to disabled persons having limited walking capabilities.

Non-Clinical Testing:
Compliance to applicable Testing Standards is as follows:
RESNA WC Vol.1 2008 DRAFT - Requirements and Test Methods for Wheelchairs (Including Scooters)
RESNA WC Vol. 2 2008 DRAFT - Additional Requirements for Wheelchairs (Including Scooters) with Electrical Systems
ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.
IEC 601-1-1 Medical Electrical Equipment, General Requirements for Safety
CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The **Jazzy Frontie** Powered Wheelchair has the same intended use and similar technological characteristics as the Jet 1 (K001970), 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 Frontie** 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

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

Pride Mobility Products Corporation
% Ms. Kimberly Blake
Official Correspondent
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

OCT 23 2009

Re: K092961
Trade/Device Name: Jazzy Frontie
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 15, 2009
Received: September 25, 2009

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.

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

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: Jazzy Frontie

Indications for Use:

The intended use of the Pride Mobility Products Corporation Jazzy Frontie 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)

FOR M. MELKERSON

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

510(k) Number K092961