K041346

Pride Mobility Products Corp.

Research & Development
330 Philadelphia Avenue
West Pittston, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

SEP - 8 2004

Exhibit 1

510 (K) Summary
Pride Mobility Products Corporation
Synergy Ultimate

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

Contact Person:
Thomas Schappert

Date Prepared:
04-30-04

Name of Device and Proprietary Name:
Synergy Ultimate / Pride Mobility

Common or Usual Name:
Seating System

Classification Name:
Physical Medicine / Wheelchair, Powered

Product Code:
ITI

Comparison to Predicate Devices:
The Synergy Ultimate is substantially equivalent to Motion Concept's TRX-CG Power Positioning System with Center-of Gravity Shifting Power Tilt, Recline, and Power Elevating Seat. They both require battery operated Powered Wheelchair bases to operate the seating system; performance characteristics and drive mechanisms are similar to achieve the same intended use function for the user to reposition and relieve pressure to achieve comfort. All safety features are equivalent.

Device Description:
The Synergy Ultimate is a battery-operated wheelchair seating and positioning system featuring a power tilt and / or a power seat elevator. The Synergy Ultimate is designed for, but not limited to Pride Mobility Products Corp. Powered Wheelchairs.

There are a variety of additional options available on the system including power recline with a skin shear reduction package or power articulating and elevating leg rests. Each feature can be used independently of each other or simultaneously to achieve the necessary repositioning of the user for pressure relief, increased respiratory function, positioning for daily activities or for other reasons deemed medically necessary. The frame is a welded steel construction and all materials used on the Synergy Ultimate meet or exceed the California 117 standard for Flame Resistant Testing.

The power tilt function allows the entire seat base and back to tilt rearward up to 55 degrees to transfer weight from the lower extremities to the upper torso. The power recline system allows the seat back to move independently of the seat base opening the back angle up to 170 degrees. The reclining seat back can also be equipped with a sliding back package that will limit the amount of skin sheer produced by the reclining of back. The power elevating seat function allows the client to elevate themselves up to 12 inches to gain additional access to their environment. The power elevating leg rests allow the clients lower extremeties to be elevated independently, combined or in conjunction with the Reclining Back. The elevating leg rests may also be equipped with an articulation feature that helps maintain proper knee to heel length during the elevation of the leg rests

The Synergy Ultimate has been designed with client safety as a priority. Actuator lock out and drive speed inhibits are incorporated into the system and monitored by the power seating control system to ensure client safety.

Intended Use:
The Pride Mobility Products Corp. Synergy Ultimate is a power positioning system designed for users who need to operate their power chair independently without assistance from an attendant. The user is able to adjust the unit to achieve comfort, pressure relief, and necessary positioning.

The Synergy Ultimate is available with any or all of the following features: power tilt, power-elevating seat, power recline and power elevating leg rests. All functions can be controlled from the user's joystick, through an attendant control device, or through an optional toggle switch.

Pride Mobility Products Corp. makes no claims to the therapeutic effectiveness of the product listed above. Pride Mobility Products Corp. strongly recommends a certified rehabilitation therapist evaluate all customers of its products.

Non-Clinical Testing:

ANSI/RESNA WC/01 Determination of Static Stability Testing
ANSI/RESNA WC/02 Determination of Dynamic Stability of Electric Wheelchairs

ANSI/RESNA WC/14 Power and Control Systems for Electric Wheelchairs
ANSI/RESNA WC/15 Documentation and Labeling
ANSI/RESNA WC/21 Requirements and test methods for Electromagnetic Compatibility
CAL 117 Section A, D, & E – Flame Resistant Testing

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The Synergy Ultimate has the same intended use and similar technological characteristics as the Motion Concepts, TRX-CG Power Positioning System, 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. The Synergy Ultimate has passed all the necessary testing procedures and is considered to be safe for user operation on Pride Mobility Products Corp. as well as other manufactures power wheelchairs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Mr. Thomas Schappert
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

Re: K041346
Trade/Device Name: Synergy Ultimate
Regulation Number: 21 CFR 890.3910
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: August 10, 2004
Received: August 13, 2004

Dear Mr. Schappert:

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.

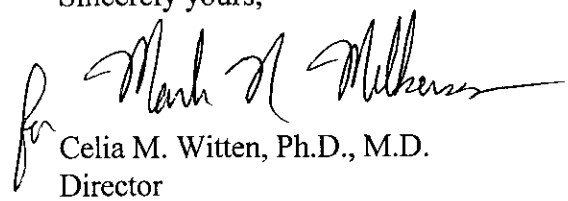
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K-041346

Device Name: **Synergy Ultimate**

Indications for Use: The Pride Mobility Products Corp. Synergy Ultimate is a power positioning seating system designed for users who need to operate their power chair and seating system independently without assistance from an attendant. The user is able to adjust the unit to achieve comfort, pressure relief, and necessary repositioning.

The Synergy Ultimate is available with any or all of the following features: Power Tilt, Power-Elevating Seat, Power Recline, and Power Elevating Leg rests. All functions can be controlled from the user's joystick, through an attendant control device, or through an optional toggle switch.

Pride Mobility Products Corp. makes no claims as to the therapeutic effectiveness of the product listed above. Pride Mobility Products Corp. strongly recommends a certified rehabilitation therapist evaluate all customers of its products.

Prescription Use ___X___ **AND / OR** **Over-The-Counter Use**_____
(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 Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041346