DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 - 2004

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

Re: K042444
Trade/Device Name: Litestream 500E Mechanical Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: August 13, 2004
Received: September 9, 2004

Dear Mr. Schappert:

This letter corrects our substantially equivalent letter of October 21, 2004 regarding the incorrect spelling of the Trade/Device Name as Lifestream. The correct spelling of the device is listed above.

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 (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); 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 continue 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 (240) 276-0120. 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,

for Mark N. Melkerson

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

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: **Litestream 500E Mechanical Wheelchair**

Indications for Use: The intended use of the Litestream 500E is to provide mobility to persons limited to a seated position that are capable of operating a mechanical wheelchair.

The Litestream 500E mechanical wheelchair enhances the mobility of users whom are partially or fully non-ambulatory.

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 Mark N Melkerson

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

510(k) Number K042444

K042444

OCT 2 1 2004

Exhibit 1

510 (K) Summary
Pride Mobility Products Corporation
Litestream 500E

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:
August 13, 2004

Name of Device and Proprietary Name:
Litestream 500E / Pride Mobility

Common or Usual Name:
Manual Wheelchair

Classification Name:
Wheelchair, Mechanical

Product Code:
IOR

Comparison to Predicate Devices:

The Litestream 500E Mechanical Wheelchair is substantially equivalent to the Sunrise Medical Quickie (K850536)

Device Description:

The Litestream 500E mechanical wheelchair is lightweight and designed to provide mobility based on the user's capabilities and needs, with propulsion by the user or an attendant. To better adapt to individual needs, the Litestream 500E is available in various seat sizes, and features component adjustments to enhance fitting and performance.

With hand-rim drive wheels in the rear, and pivoting front casters, the Litestream 500E steers according to typical mechanical wheelchairs, and features common wheelchair components, including a seat frame, backrest, armrests, legrests, and wheel locks.

The Litestream 500E performs well indoors, and maintains its performance on firm, smooth, surfaces, as well as those that are free of steep angles and obstacles. For durability and less weight, the frame material is aluminum, with a seat and backrest upholstery fabric that meets the California CAL177 Standard for flammability. The Litestream 500E Owner's Manual contains descriptions and specifications toward meaningful use, operation, and care of the wheelchair.

Intended Use:

The intended use of the Litestream 500E is to provide mobility to persons limited to a seated position that are capable of operating a mechanical wheelchair.

The Litestream 500E manual wheelchair enhances the mobility of users who are partially or fully non-ambulatory.

Non-Clinical Testing:

ANSI/RESNA WC/01 Determination of Static Stability Testing
ANSI/RESNA WC/03 Test Methods and Requirements for the Effectiveness of Brakes
ANSI/RESNA WC/05 Determination of Overall Dimensions and Turning Space
ANSI/RESNA WC/08 Static Impact, Fatigue, and Strength Tests
ANSI/RESNA WC/11 Test Dummies
ANSI/RESNA WC/13 Coefficient of Friction
ANSI/RESNA WC/15 Documentation and Labeling
ANSI/RESNA WC/93 Maximum Overall Dimensions
Cal 117 – Flammability Testing

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The Litestream 500E has the same intended use and similar technological characteristics as the Quickie. 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 500E mechanical wheelchair is substantially equivalent to the predicate device.