I.H.S. INTERNATIONAL

HEALTHCARE SOLUTIONS, INC.

SEP 20 1996

510(K) SUMMARY
Standup Wheelchair

November 29, 1995

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K955547

- Name of Device: **Wheelchair, Standup**
- Proprietary Name: CHIPS Standup Wheelchair
- Common Name :Standup Wheelchair
- Classification Name: Wheelchair, Standup

- Legally marketed device to which our company is claiming equivalence: Levo, trade name, Mobil LCM, located at Bleicheweg 5, CH-5605 Dottikon, Switzerland, and I.D.C., trade name, Lifestand, located at LDC Corp. of America, Inc., 780 B2 Primos Avenue, Folcroft, PA. 19032.

- Description of Device: Standup Wheelchair. See attached letter.

- Intended Use of Device: See attached description letter.

- Summary of technological characteristics of our device compared to the predicate device: Refer to Section 4 - Technical Specifications and Test Reports.

- Brief description of the nonclinical tests and how their results support a determination of substantial equivalence: Refer to Section 4 - Technical Specifications and Test Reports.

Very truly yours,

Fred DiVito
President

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CHIPS WHEELCHAIR STANDUP
DESCRIPTIVE INFORMATION

510(K) Pre Market Notification

The specific intended use of the Power Standup Wheelchair, which is the subject device, shares many similarities to pre-existing or predicate devices.

The I.H.S. Chips Power Standup Wheelchair helps promote mobility for its intended user, who typically is limited in full use of lower extremities. These limitations will usually be of long or permanent duration and caused by numerous medical conditions ranging from spinal cord injuries, broken bones, stroke, as well as numerous other disabilities.

Prolonged periods of sitting without shifting or reducing pressure on the buttocks, especially the ischium area can cause or contribute to the development of pressure sores. In addition, prolonged sitting can promote atrophy of inactive muscles, which may lead to long term weakness, or in general, physical degeneration.

The subject device, through a safe and effective lifting motion, helps promote well-being by enabling the user at will to safely and securely change his posture from a sitting position to fully upright, allowing the bodies natural articulation to accomplish this. The physical, as well as the psychological benefits to the user, become evident when analyzing the degree of self-independence the user is now capable of achieving.

Our subject device provides mobility and lift independently, by incorporating a joy stick type controller, which sends power to electric gear motors..This in turn directly drives two rear wheels, which propel the device, (as well as a lifting actuation, which accomplishes the lifting action).

This is very typical and common to predicate devices like those manufactured by Levo, trade name Mobil LCM, located at Bleicheweg 5, CH-5605, Dottikon, Switzerland, and I.D.C., trade name, Lifestand, located at LDC Corp. of America, Inc., 780 B2 Promos Ave., Folcraft, PA 19032 (Refer to Section 3).

The controller on the subject device, similar to predicate devices, incorporates safety features such as, speed control, sensitivity control, battery life indicator and power on and off indicator light. It is manufactured by Penny & Giles, Drives Technology Ltd., 1 Airspeed Road, Christchurch, Dorset, BH23 4HD England. (PG8 Series detailed information in Section 4).

The above controller features are typically customized by the rehabilitation dealer who has been instructed in the use and function of the product and who in turn instructs the end user in the use and function of the Standup Chair.

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The main product components include a steel tubular welded frame which supports a sitting surface. (Refer to Section 4).

Both the seat and the back support are made of a durable nylon material. In addition, the frame incorporates adjustable and removable armrests providing support for the user occupant and removable to facilitate transfer into and out of the wheelchair.

Both leg rests and foot rests are designed in a unitized construction to structurally support the users body weight while standing.

The foot rest assembly is designed to swing away to facilitate entry and exit to the Standup chair and the assembly is removable to facilitate transportation of the device. The above described features are typical in predicate devices.

Power is supplied to the device by incorporating two 12 volt wet or gel cell batteries providing a 24 volt system. This in turn supplies power to two rear mounted direct drive motors, both incorporating electromechanical automatic brakes. The motors in turn provides power to a sealed gear box which transfers power to the rear wheels.

The Penny & Giles PG 8 Programmable control system provides reliable, precise control and conforms to the latest International Standards. It has plenty of drive to cope with curbs or hill climbing by continually monitoring motor voltage and current. It readily maintains constant speed over demanding uneven terrain and prevents unwanted rolling on slopes. It handles currents from 20 Amps to 70 Amps per channel, is fully programmable, incorporates true charge battery level indicator, has user speed and response controls, and a horn to alert others.

It incorporates sophisticated diagnostics to facilitate repair and provide speed stability on slopes for safety. It incorporates hand tremor dampening for users who have poor motor control. It has been manufactured to meet or exceed ISO 9001 and designed to ISO 7176/14 and has been approved by International Regulations known as TUV and has surpassed Swedish Handicap Institute Approval. (See Section 4, Technical Specifications and Testing for more details).

Fred DiVito pres.

Fred DiVito
November 29, 1995

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