LifeStand "Vivre-Debout"
Rond-point de Rosarge
40, rue Palverne
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EXHIBIT #1

K042596

JAN 26 2005

# 510(K) SUMMARY

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:_____.

1. **Submitter's Identification:**

**Lifestand**
**Rond-point de Rosarge**
**40, rue Palverne**
**F 01700 LES ECHETS-FRANCE**

Date Summary Prepared: September 06th, 2004

2. **Name of the Device:**
LSA Helium

3. **Common or Usual Name:**
manually propelled standup wheelchair

4. **Device Description:**
The LSA Helium is a manually propelled standup wheelchair. It is propelled and steered by varying the speed of the two back wheels. Front castors support the front of the chair and allow indirect steering through the turning back wheels. A gas-spring-system supports the customer in putting the seat manually into a seating or standing position.

| | | |
|---|---|---|
| Maximum end-user weight | : | 100 kg |
| Wheelchair width | : | 36/38/40/42/44/46cm |
| Wheelchair seat depth | : | 40 to 50 every 2 cm |
| Frame | : | Rigid, in magnesium, epoxy paint |
| Seat | : | Depth adjustable, with sore proof cushion |
| Backrest | : | Inclinable. Folds down for transport |
| Upholstery | : | Polyester fireproof material (M4), washable |
| Foot-rests | : | Height adjustable |
| Front wheels | : | Ø 125mm x 29mm, solid |
| Rear wheels | : | Ø 600mm x 25mm, 1000kPa |
| Brakes | : | Hand, by pushing |
| Propulsion | : | Manual |
| Elevation | : | Manual assisted by gas-powered springs, adjustable according to the user's weight. |
| Rear stabilization | : | Anti-tip wheels (optional). |
| Idle weight | : | 17,9kg |

LIFESTAND

5. **Intended Use:**
The LSA Helium offers manually operated seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifibia, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.

6. **Comparison to Predicate Devices:**
The LSA Helium is substantially equivalent to the standup wheelchair LAE (LEVO Active Easy) by LEVO, K971873

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**
To approve the performance of the LSA Helium, tests according to current applicable standards where performed at test-laboratories of European notified bodies:

| | |
|---|---|
| EN 12182: 1999 | Technical aids for disabled persons. General requirements and test methods |
| EN 12183: 1999 | Manually propelled wheelchairs. Requirements and test methods |
| ISO 7176-1: 1999 | Wheelchairs. Determination of static stability |
| ISO 7176-3: 1988 | Wheelchairs. Determination of effectiveness of brakes |
| ISO 7176-5: 1986 | Wheelchair tests. Methods for determination of overall dimensions, mass and turning space |
| ISO 7176-7: 1998 | Measurement of seating and wheel dimension |
| ISO 7176-8: 1998 | Wheelchairs. Requirements and test methods for static, impact and fatigue strengths |
| ISO 7176-15: 1996 | Wheelchairs. Requirements for information disclosure, documentation and labeling |
| ISO 10993-5: 1999 | Biological evaluation of medical devices. Tests for in vitro cytotoxicity |
| NFP 92503: | flammability |
| NFP 92505: | flammability |
| ISO 6941: 2003 | Textile fabrics. Burning behavior. Measurement of flame spread properties of vertically oriented specimens |

8. **Discussion of Clinical Tests Performed:**
Clinical tests were not performed

9. **Conclusions:**
Lifestand believes that the LSA Helium is substantially equivalent to the predicate and is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2005

Ms. Stephanie D. Bankston
Official Correspondent for Lifestand
Lifestand
10925 Beamer #290
Houston, Texas 77089

Re: K042596
Trade/Device Name: LSA Helium
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: II
Product Code: IPL
Dated: January 11, 2005
Received: January 14, 2005

Dear: Ms. Stephanie D. Bankston

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 (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/industry/support/index.html.

Sincerely yours,

for 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**



**510(k) Number (if known):** K042596

Device Name: LSA Helium

**Indications For Use:**

The LSA Helium offers seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.

**Prescription Use** X
**(Per 21 CFR 801 Subpart D)**

**OR**

**Over-The Counter Use**
**(21 CFT 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 Milhous

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

**510(k) Number** K042596