DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1997

Mr. Thomas Raeber
LEVO AG Dottikon
Bleicheweg 5
CH-5605 Dottikon
Schweiz, Switerland

Re: K973951
LEVO Compact-Easy LCE
Regulatory Class: II
Product Code: IPL
Dated: October 9, 1997
Received: October 16, 1997

Dear Mr. Raeber:

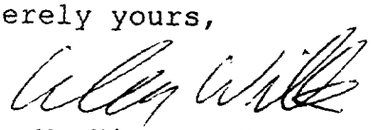
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): **K973951**

Device Name: **LEVO** *compact-easy LCE*

Indications For Use:

- The LEVO stand-up wheelchair is a product which changes peoples position from seating to standing and standing to seating.

Target population:

- For whole those who need a wheelchair and can not stand on their on feet such as people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc..

Design:

- An electrical power suported stand-up mechanism is integrated in a manual driven wheelchair which allows the user to stand up easily when and where ever he wants to.

Material:

- Main frame: Colour painted aluminium.
- Major stressed parts: Reinforced brass casting.
- Upholstery: Flame impeded.
- Battery: 2 Gel, sealed lead acid battery (12V/2.9Ah in series=24V/2.9Ah)
- Stand-up motor: Linak Power Drive LA 28.405-150-24-001 24 VDC, 2500N

Performance:

- The **LEVO** *compact-easy LCE* allows the user to stand up easily when and where ever he wants to. Whether to reach things without help of others, whether take part in discussions standing up and show influence, whether just to do daily therapy individually.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973951

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)