K051387

p. 1/2

JUN 10 2005

510(k) Summary of Safety and Effectiveness

LEVO *comfort II*

Submitter:	LEVO AG P.O. Box 1272 Anglikerstrasse 20 CH-5610 Wohlen, Switzerland
Phone: Fax:	+41 56-6184411 +41 56-6184410
Contact Person:	Mr. Markus Burger, Head of R&D Mr. Thomas Raeber, Managing Director
E-Mail-Address:	m.burger@levo.ch raeber@levo.ch
Device Name:	**LEVO** *comfort II*
Classification Name:	Electrical Power Wheelchair, Stand-up
Identification of Predicate Devices:	**LEVO** *mobil* LCM (K 963817) Quickie Freestyle (K 031289)
Intended Use:	The **LEVO** *comfort II* stand-up power wheelchair is a product which changes people's position from sitting to Standing and Standing to sitting but also any position in between. The product provides indoor and outdoor mobility.
Description of the Device:	The **LEVO** *comfort II* power wheelchair is centre wheel driven, battery powered, motor driven and is controlled by the PG Drives Technology's power wheelchair controller "VSI" The Joystick is integrated in the Controller. The wheelchair is powered by: two 12V/26Ah, two 12V/40Ah or four 12V/26Ah batteries with a theoretical driving range of 14km (26Ah), 20km (40Ah) or 28km (56Ah) on the fully charged batteries.

The wheelchair consists of the following basic sub-sections:

- Base with two direct-drive units with integrated parking brakes, two 12V/26Ah, two 12V/40Ah or four 12V/26Ah, two 14"x2%" rear wheels and two 8"x2" front wheels.
- PG Drives Technology's power wheelchair controller "VSI"
- Seating System including stand-up mechanisms and actuator.

The base is of welded steel construction and includes the base frame, front castor wheels, rear driving wheels with drive unit (motor/gear/brakes) and batteries. The motor Controller is mounted to the left or right armrest, depending on the user's needs.

Safety and Effectiveness:

The **LEVO** *comfort II* was basically developed on experience of the **LEVO** *mobil LCM*. However being able to provide additional outdoor mobility as well as further improvements in the geometric for an excellent biomechanical response to the user's body. The only modifications are simply colour and design changes. So the **LEVO** *comfort II* has in substantial the same technological characteristics and the same safety and effectiveness as the predicate device(s) and the minor changes declared in the Submission do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2005

Levo AG
C/o Mr. Stefan Priess
TUV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K051387
Trade/Device Name: LEVO comfort II
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: II
Product Code: IPL
Dated: May 25, 2005
Received: May 27, 2005

Dear Mr. Preiss:

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,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): not known

Device Name: LEVO *comfort II*

Indications for Use: The **LEVO** *comfort II* stand-up power wheelchair may be of interest for any individuals who needs a power wheelchair and can not stand up on their own such as people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc..

Intended use: The **LEVO** *comfort II* stand-up power wheelchair is a product which changes people's position from sitting to Standing and Standing to sitting but also any position in between. The product provides indoor and outdoor mobility.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use XX (21 CFR 801 Subpart C)

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

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

510(k) Number K051387