3. Summary

Common Device Name: Elevator, Wheelchair

Trade Name: Genesis Vertical Platform Lift

Predicate Device: V-1504 Vertical Platform Lift (K960739) as manufactured by Services Industriels Savaria Inc.

See the attached product literature.

Device Description: The Genesis Vertical Platform Lift is designed to transport persons with a mobility disability, either in a wheelchair or ambulatory, up and down between levels of a residential or public facility.

It can be located within with its own integrated shaftway enclosure, located within a building shaftway or be unenclosed other than guarding around the platform area. It is designed for both indoor and outdoor locations.

The Genesis has a capacity of 750 lbs to accommodate a person in a wheelchair and an attendant. The lifting height is up to 14 feet. It is available with a chain hydraulic drive system or an acme screw drive system. Backup systems are available for emergency operation and evacuation.

All controls are low-voltage constant pressure. Use may be restricted to authorized persons with key switches located on the control panels.

The Genesis is built in accordance with ASME A17.5 Electrical Code for Elevating Devices and the ASME A18.1 Safety Standard for Platform Lifts and Stairway Chairlifts.

See the attached product literature..

Intended Use: The Genesis Vertical Platform Lift is intended to mechanically transport persons with a mobility disability, either in a wheelchair or ambulatory, up and down between levels of a residential or public facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2004

Mr. Norm Cooper
Director of Marketing and Customer Relations
Garaventa Accessibility
7505 -134A Street
Surrey, British Columbia V3W 7B3

Re: K033469
Trade/Device Name: Genesis Vertical Platform Lift
Regulation Number: 21 CFR 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: II
Product Code: ING
Dated: December 4, 2003
Received: December 5, 2003

Dear Mr. Cooper:

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 (301) 594-4659. 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, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) Number: K033469

Device Name: Genesis Vertical Platform Lift

Elevator, Wheelchair

Indications for Use:

The Genesis Vertical Platform Lift is intended to mechanically transport persons with a mobility disability, either in a wheelchair or ambulatory, up and down between levels of a residential or public facility.

Prescription Use _____ AND/OR Over-the-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (Part 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)

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

K033469

(Optional Format 1-2-96)