

JUL - 1 1998

K981486

510(k) SUMMARY

(In accordance with 21 C.F.R. §807.92)

Submitted by: Barnes, Richardson & Colburn
1225 Eye Street, N.W. #1150
Washington, D.C. 20005

Tel: (202) 457-0300
Fax: (202) 331-8746

Contact: Alyssa Chumnanvech

Date Prepared: April 23, 1998

Common Device Name: Inclined Platform Lift

Trade Name: STAIR-LIFT

Predicate Device: Savaria ES-125 STAIR PLATFORM LIFT
K960276

Subject Product
Description:

The STAIR-LIFT is an unenclosed inclined platform lift designed to carry a wheelchair and its occupant or a mobility-impaired person seated on a folding seat between floors in a public or private facility. There are currently three different models designed to address the nature of the stairway involved in its use. The GSL-1 model is designed for straight and turning stairways. It follows the inside radius of a stairwell. The GSL-2 model is designed strictly for straight stairways, and the GSL-3 model is designed for complex turning stairways that follow either the inside or outside radius of the stairwell. Each of the three models is accessible via one of three types of platform/ramp units. These platform/ramps are raised either manually or electrically.

The GSL-1 and GSL-3 (turning) models use two parallel steel tubes, custom built for the stairway, to support their platforms. The tubes contain a continuous loop of wire haul rope that attaches to the platform through a slot in the upper tube. An electrical motor at the top of the system turns a drive cog, which moves the wire haul rope, carrying

the wheelchair platform up and down the stairway. Delrin spheres and knuckles are affixed to the rope to keep it in the center of the tubes.

The GSL-2 (straight) model uses three square structural steel rails to support the platform. The top two rails contain a roller chain which is held in a continuous loop by aircraft cable. The chains are attached to the platform through a slot in the upper rail. The bottom rail guides the platform, while an electrical drive motor at the top of the system propels the chains.

Intended Use:

Garaventa's STAIR-LIFT is intended to mechanically transport one person in a wheelchair or in a fold-down seat up and down stairs in a private or public facility either indoors or outdoors.

Product Comparison Table:

	SAVARIA ES-125	STAIR-LIFT GSL
Intended Use	to mechanically transport one mobility-impaired person up and down stairs in a private or public facility	to mechanically transport one mobility-impaired person up and down stairs in a private or public facility
Indoor or Outdoor Use	yes	yes
ANSI A17.1 Compliant	yes	yes
Electric Motor	yes	yes
Type of Drive Unit	chain drive sprocket (standard on ES-125 Plus model)	chain drive sprocket (GSL 2) wire rope sprocket (GSL 1 and 3)
Drive Unit Power	0.373 kW (1/2 HP)	0.75 kW (1 HP) or 1.12 kW (1.5 HP)
Mains Power	208-230 volts AC	208-240 volts AC
Electric Control Board	yes	yes
Optional Manual Operation	yes	yes
Key-Operated Station Controls	yes	yes
On-Board	yes	yes

	SAVARIA ES-125	STAIR-LIFT GSL
Control with Key Switch		
Continuous Pressure Directional Controls	yes	yes
Under Platform Sensing to Stop Lift Upon Contact with Obstacle	optional only	standard on all three models; STAIR-LIFT also equipped with: (1) under hanger sensing to stop movement upon contact with obstacle upon being called to/from landing areas, (2) multi-directional ramp sensing to detect pressure from inside the platform ramps to ensure passenger positioned safely before lift begins movement, and (3) overspeed safety device
Optional Fold-Down Seat for Non-Wheelchair Passengers	yes	yes
Foldable Platform	yes	yes
Automatic Access Ramp	yes	yes

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Alyssa Chumnanvech
•Barnes, Richardson & Colburn
Representing Garaventa (Canada) Limited
1225 Eye Street, N.W.
Suite 1150
Washington, DC 20005

Re: K981486
Trade Name: STAIR-LIFT
Regulatory Class: II
Product Code: ING
Dated: April 24, 1998
Received: April 24, 1998

Dear Ms. Chumnanvech:

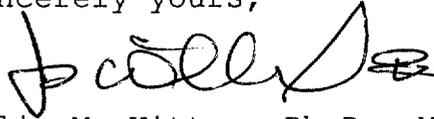
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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,



fr 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

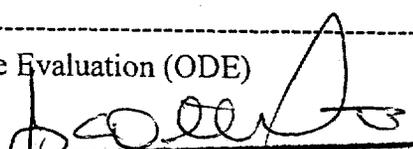
Device Name: Stairway Elevator

Indications for Use:

The STAIR-LIFT is intended to mechanically transport one person in a wheelchair or in a fold-down seat up and down stairs in a private or public facility either indoors or outdoors.

(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 *K99142*
510(k) Number _____

Prescription Use *X*
(Per 21 C.F.R. § 801.109)

OR

Over-the Counter Use _____