K032880 1/2

Summit Lifts, Inc.

23615 S. 291 Highway Harrisonville, Mo 64701
Ph: 816-887-9919 Fax: 816-380-5759
"Taking you to new heights"

NOV 1 0 2003

510(k) SUMMARY

Submitted by:	Summit Lifts, Inc. 23615 South 291 Highway Harrisonville, MO 64701
Contact:	Kent T. Perry Telephone: (913) 498-1700 Facsimile (913) 498-8488
Date Prepared:	August 29, 2003
Subject Device:	Summit™Stairway Lift
Predicate Devices:	Silver-Glide®
Subject Product Description:	The Summit™Stairway Lift is a stairway chairlift designed to carry a rated load of 300 lbs. directly up and down a set of stairs in a residence. The Summit™Stairway Lift is designed to travel a maximum 20 feet at a rated speed of 22 feet per minute. Foot rest safety sensors stop the lift in either direction should it strike anything on the stairs. The chair can be swivelled at the top and bottom landing for easy and safe access to the seat. A swivel safety switch makes sure the seat is in the proper position before allowing the unit to run. The Summit™Stairway Lift can be transformed from a left hand to a right hand side on the site of installation within minutes. The chairlift can also be folded in the up position as to facilitate access to the staircase. Seat belt is standard. The lifting system is aircraft grade lifting cable on a grooved aluminum drum. The lifting system has safeties to stop the lift if the cable is not properly tensioned. Limit switches shut the unit off in the same place at the top and bottom of the stairs automatically. Constant pressure controls are designed to stop the lift immediately if and when controls are released. Features include:

- Cable driven
- 180 degree swivel at both landings
- Adjustable seat height
- Seat belt

- Padded seat folds up when not in use
- Fold up footrest adjusts to two different heights
- Obstacle sensor
- Swivel seat actuator
- Arm control switch
- 110 VAC grounded outlet
- Magazine rack

Intended Use:

This product will be used by the patient to assist in navigating a specific set of stairs. This is a self-contained product that is mounted to the tread of a staircase. This design offers easy installation. The typical user is someone who has limited function of their knees, hips or ankles and/or has trouble bending these joints. Other users include rehabilitated stroke victims, those inflicted with MS, arthritis, heart disease, and those who cannot handle the exertion of walking up and down stairs. The unit may be recommended by doctors or physical therapists, for those who are recuperating but a large number of users acquire a stairway elevator just because it eases the burden of climbing stairs, improving their quality of life. For those who are wheelchair bound, it requires that they be able to transfer and is usually an option only if the physical limitations of the residence prohibits a vertical elevator.

Product Comparison:

The Summit™Stairway Lift is substantially equivalent to the the Silver-Glide ®-HD Both products are used by the patient to assist in navigating a specific set of stairs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2003

Summit Lifts, Inc.
C/o Mr. Kent T. Perry
Kent T. Perry & Co., LC
7300 W. 110th St.
Overland Park, Kansas 66210

Re: K032880
Trade/Device Name: Summit™ Stairway Lift
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: II
Product Code: ILK
Dated: September 11, 2003
Received: September 15, 2003

Dear Mr. Perry:

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,

Miriam C. Provost

for Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS OF USE STATEMENT

This product will be used by the patient to assist in navigating a specific set of stairs. This is a self-contained product that is mounted to the tread of a staircase. This design offers easy installation. The typical user is someone who has limited function of their knees, hips or ankles and/or has trouble bending these joints. Other users include rehabilitated stroke victims, those inflicted with MS, arthritis, heart disease, and those who cannot handle the exertion of walking up and down stairs. The unit may be recommended by doctors or physical therapists for those who are recuperating, but a large number of users acquire a stairway elevator just because it eases the burden of climbing stairs, improving their quality of life. For those who are wheelchair bound, it requires that they be able to transfer and is usually an option only if the physical limitations of the residence prohibits a vertical elevator.

Miriam C. Provost

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

510(k) Number K032880