K113065
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BELLA ELEVATOR

FEB 2 2 2012

Bella Elevator, LLC
8915 N. Pioneer Rd
Peoria, IL 61615
Phone: (309)-689-8090
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510K Summary

Contact Person:

Rick Crane, President

Date: October 3, 2011

Re: 510K Summary

Name of Device:

RL, UL, SL, EL, and EPL Vertical Platform Lifts

Common or Unusual name:

Wheelchair Elevator or Vertical Platform Conveyance (VPC)

Classification Name:

Wheelchair Elevator (CFR 890.3930)

Predicate Device:

Bruno VPL 3100 Vertical Platform Lift (K061514)

Summit Harmar RPL/CPL Vertical Platform Lift (K091881)

Savaria, Inc V-1504 Vertical Platform Lift (K960739)

Garaventa Genesis Platform Lift (K033469)

BELLA ELEVATOR

510(K) Summary Cont'd:

Intended Use:

The Bella Elevator, LLC vertical platform lift models RL, UL, SL, EL, EPL are 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.

Device Description:

The Bella Elevator, LLC vertical platform lift models RL, UL, SL, EL, EPL are 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.

The model EL and EPL are located within with their own integrated enclosure. The model SL is located within a preexisting building shaft way. The UL model is unenclosed, other than guarding around the platform area. The RL model can conform to any of the aforementioned applications found in a residence. These models are designed for both indoor and outdoor applications.

Each referenced model has a capacity of 750 lbs to accommodate a person in a wheelchair and an attendant. The lifting height is up to 14 feet. Each 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 switch located on control panels.

Performance Data:

The Bella Elevator, LLC Vertical Platform Lift models RL, UL, SL, EL, and ELP fully comply with the applicable sections of the following National Safety Standards:

ASME A18.1- Safety Standard for Platform Lifts and Stairway Chairlifts

ASME 17.5- Electrical Code for Elevating Devices

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bella Elevator, LLC
% Mr. Rick Crane
President
8915 North Pioneer Road
Peoria, Illinois 61615

FEB 22 2012

Re: K113065
Trade/Device Name: Vertical Platform Lifts Models RL, UL, SL, EL, and EPL
Regulation Number: 21 CFR 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: II
Product Code: ING
Dated: February 8, 2012
Received: February 15, 2012

Dear Mr. Crane:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113065

Device Name: Vertical Platform Lifts, Models RL, UL, SL, EL, EP

Indications For Use:

The Bella Elevator, LLC vertical Platform lift models RL, UL, SL, EL, EPL are 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.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113065