K042699

510(k) SUMMARY

MAR 16 2005

Gator Custom Mobility, Inc.
510 (k) Premarket Notification
Power Gurney

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Gator Custom Mobility, Inc.
501 NE 23rd Ave.
Gainesville, FL 32609
Phone: (352) 373-9673
Fax: (352) 271-9070

Contact Person: Gregory S. Sims
Vice President

Date Prepared: September 8, 2004

Name of Device and Name/Address of Sponsor:

Ability Power Gurney

Gator Custom Mobility, Inc.
501 NE 23rd Ave.
Gainesville, FL 32609
Phone: (352) 373-9673
Fax: (352) 271-9070

Common or Usual Name:
Powered Wheeled Stretcher

Classification Name:
Powered Wheeled Stretcher

Regulatory Class:
Class II

Predicate Devices:
Products that are substantially equivalent to the Ability Power Gurney are the Stryker Powered Wheeled Stretcher (K022309, August 13, 2002) and the Invacare Storm Series power wheelchair (K993413, October 12, 1999)

Intended Use:
The intended use of the Ability Power Gurney is to provide mobility to persons limited to a prone position, that have the capability of operating a powered wheelchair

Technological Characteristics and Substantial Equivalence

A. **Device Description**

The Ability Power Gurney is a battery powered, motor driven device consisting of a platform mounted on a wheeled frame that is designed to provide mobility and transportation to physically challenged persons that may be restricted to a horizontal position. The device may have patient securement straps and supports for fluid infusion equipment.

A Penny and Giles VSI controller joystick and a 70amp controller is used to operate the Ability Power Gurney, the same as the predicate device, the Invacare Storm Power Wheelchair. The Ability Power Gurney is powered by two 12VDC, Group U-1 Gel Batteries and has a range of up to 15 miles on a full charge. The base of the stretcher is made of welded steel construction.

The Ability Power Gurney and the predicate both have a caster mounted design with a variable height top surface. The top may be controlled by the client for pressure relief and access to different heights. Optional material meets California 117 standards for fire retardancy.

B. **Substantial Equivalence**

Products which are substantially equivalent to the Ability Power Gurney are the Stryker Powered Wheeled Stretcher (K022309, August 13, 2002) and the Invacare Storm Series power wheelchair (K993413, October 12, 1999)

Performance Data

The motors and control mechanisms for the Ability Power Gurney, the same that are on the Invacare Storm power wheelchair, meet the applicable requirements specified in the Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/14 (1991) and ISO Standard ISO 7176:1993 (E) "ISO Standard, Wheelchairs-Requirments and Test Methods for the Power and Control Systems of Electric Wheelchairs.

The Ability Power Gurney will comply with the following voluntary standards:

IEC 601-1-1	Medical Electrical Equipment- Part 1: General Requirements for Safety 1: Safety Requirements for Medical Electrical Systems
IEC 601-1-2	Medical Electrical Equipment- Part 1: General Requirements for Safety 2: Electromagnetic Capability- Requirements and Tests
UL 2601-1	Standard for Medical Electrical Equipment-Part 1: General Requirements for Safety
CAN/CSA-C22.2	No. SD1.1-M90, Medical Electrical Equipment Part 1: General Requirements for Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Mr. Gregory S. Sims
Vice President
Gator Custom Mobility, Inc.
501 NE 22RD Avenue
Gainesville, Florida 32609

Re: K042699
Trade/Device Name: Ability Power Gurney
Regulation Numbers: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Codes: ITI
Dated: March 9, 2005
Received: March 11, 2005

Dear Mr. Sims:

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,

for Miriam 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): K042699

Device Name: Ability Power Gurney

Indications For Use:

The indication for use of the Ability Power Gurney is to provide mobility to persons limited to a prone position, that have the capability of operating a powered wheelchair.

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

510(k) Number K042699