JUL - 6 2009

510(K) SUMMARY FOR ALTIMATE MEDICAL'S EASYSTAND BANTAM

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is K091242.

Date: April 23, 2009

Submitted by: Invacare Corporation
Registration No. 1525712
One Invacare Way
Elyria, Ohio 44035-4190

Manufacturer: Altimate Medical
Registration No. 2183634
262 West First St.
Morton, MN 56270

Telephone: 440-329-6356
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Contact Person: Mr. Carroll Martin

Trade Name: EasyStand Bantam

Common Name: Electric lift chair

Classification Name: Chair, positioning, electric per 21 CFR 890.3110

Legally Marketed Predicate Device(s): Altimate Medical EasyStand Evolv; K062402 September 21, 2006

Device Description: The EasyStand Bantam is a standing frame for indoor use that allows users with various degrees of physical disability to be supported in a standing, weight-bearing position. The device is a sit-to stand stander with the option of supine positioning. The optional Shadow Tray supports the user from sitting to standing and can be used as a desk/workstation in the seated and/or standing position. The device comes standard with two options to raise the seat, manually and electrically. The device comes in two models, extra small (accommodating individuals ranging in height from 28" – 40" (71cm – 102 cm) and up to 50lbs (23kg) and small (accommodating individuals ranging in height from 36" – 54" (91cm – 137 cm) and up to 100lbs (23kg).

Intended Use: To assist persons who have difficulty rising from a seated position to a standing position and is indicated for persons weighing between 50 – 100 lbs., including pediatrics.

Substantial Equivalence: Products that are substantially equivalent to the Altimate Medical EasyStand Bantam is the Altimate Medical EasyStand Evolvo, K062402, September 21, 2006

The EasyStand Bantam is comparable to the EasyStand Evolv in its intended use, construction and functionality. The intended use of providing support for a person in a standing position, providing a means for a person to rise from a seated to a fully standing position and offering a method of exercising the body remains the same between the two devices. The power lift feature is the same in both devices in that elevation is accomplished either manually by a user operated hydraulic oil cylinder or electrically by a battery powered linear actuator motor that is activated by a hand pendant. The main differences between the two devices are as follows:

- The user population. The EasyStand Evolv is intended for larger persons (accommodates individuals ranging in height from 5' to 6'2" (152cm – 188 cm) and up to 280lbs (127kg) and the EasyStand Bantam is intended for smaller individuals, including pediatrics (accommodates individuals ranging in height from 28" – 40" (71cm – 102 cm) and up to 50lbs (23kg) and individuals ranging in height from 36" – 54" (91cm – 137 cm) and up to 100lbs (23kg). ranging from addition of the power lift feature.
- The EasyStand Bantam comes standard with a gas cylinder to allow for seat elevation that can be actuated only by the caregiver.
- The EasyStand Bantam has a supine position option for those users who don't have the neck or head support to allow them to tolerate an upright position for long periods.

Performance Standards: Although no performance standards or special controls have been developed under Section 514 of the FDC Act for electric positioning chairs, Altimate Medical has chosen to test the EasyStand Bantam against the standards as referenced in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Altimate Medical, Incorporated
% Mr. Carroll L. Martin
Regulatory Affairs Manager
Invacare Corporation
One Invacare Way
Elyria, Ohio 44035-4190

JUL - 6 2009

Re: K091242
Trade/Device Name: EasyStand Bantam
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric Positioning Chair
Regulatory Class: II
Product Code: INO
Dated: May 15, 2009
Received: May 19, 2009

Dear Mr. Martin:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Mark N. Melkerson D.D.S.

Mark N. Melkerson
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):

Device Name: EasyStand Bantam

Indications for Use: The Altimate Medical EasyStand Bantam is intended to assist persons who have difficulty rising from a seated position to a standing position and is indicated for persons weighing between 50 – 100 lbs., including pediatrics.

Prescription Use ___✔___ AND/OR Over-The-Counter Use _____
(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 K091242