SEP 2 1 2006

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

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 K062402.

Date: August 15, 2006

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: 440-326-3115
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Contact Person: Mr. Ronald Clines

Trade Name: EasyStand Evolv

Common Name: Electric lift chair

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

Legally Marketed Predicate Device(s): Altimate Medical StandEX; K885343, May 1, 1989
Invacare Lift Chair; K002171, August 10, 2000

Device Description: The EasyStand Evolv is a modular 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 modular and is configured around a centralized seat. It incorporates pivot points that allow a user to rise from a fully seated to a fully standing position. Pivot action is such that shear between the user, seat and seat back is minimized. Device is modular in that multiple uses of the device can be accommodated depending on the overall configuration of the device. Current modules allow for passive standing (Basic), workstation use at an elevated or seated position (Shadow Support Tray) and standing with leg exercise (Glider).

Elevation action is provided by one of two means. The standard device utilizes a user controlled hydraulic pump. The optional electrical version uses a low voltage motor-driven linear actuator that is powered by two 12-Volt batteries and actuated by a hand held control pendant. On the electrical

version, the patient or a care provider activates the hand held control pendant to change the position of the seat. The electric version also provides an emergency release. Recharge of batteries is accomplished by connection of an external battery charger to the control pendant.

The EasyStand Evolv is designed for indoor use and will accommodate individuals ranging in height from 5' to 6'2" (152cm – 188 cm) and up to 280lbs (127kg)

Models available
EasyStand Evolv – Basic
EasyStand Evolv – Glider
EasyStand Evolv– Shadow Support Tray

Supporting these three basic models are additional seating, postural supports and positional attachments that allow proper fit of the device to accommodate a patients particular medical condition. The powered lift feature (Pow'r Up) can be added to any of the three basic models. Fit of the device is to be determined only by a qualified therapist or physician.

Intended Use: To assist persons who have difficulty rising from a seated position to a standing position.

Substantial Equivalence: Products that are substantially equivalent to the Altimate Medical EasyStand Evolv are the Altimate Medical StandEx (K885343, May 1, 1989) and the Invacare Lift Chair (K002171, August 10, 2000).

The EasyStand Evolv is comparable to both the Invacare Lift Chair and the StandEx. It is comparable to the StandEx device 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 (the Glider model) remains the same between the two devices. The difference between the two devices is the addition of the power lift feature. This power lift feature is comparable to the lift feature in the Invacare Lift Chair in that they both use an electrically powered, low voltage DC, linear mechanical worm drive actuated via a hand held pendant to adjust the seat. Both devices also have the same intended use. The differences between the EasyStand Evolv and the Invacare Lift Chair are that the main electrical power input needed to operate the actuators comes from a battery for the EasyStand Evolv, but for the Invacare Lift Chair, it comes from AC power converted to low voltage DC power; the fact that the EasyStand Evolv seat is covered with Dartex (a polyurethane transfer coating on weft knitted fabric) and the Invacare Lift Chair has a fabric upholstered seat; that the Invacare Lift Chair offers no method of exercise; and that the EasyStand Evolv supports the user to allow for passive standing.

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 Evolv against the following standards:

BS EN 12182:1999 Part 1 Medical Electrical Equipment General Requirements for Safety
IEC/EN 60601-1: 1998; A1:1991; A2:1995 Part 1 Medical Electrical Equipment General Requirements for Safety

UL 60601-1:2003 First Edition and CAN/CSA 22.2 No. 601.1-M90 Standard for Electrical Medical Equipment Part 1: General Requirements for Safety

Substantial Equivalence Discussion

Features	EasyStand Evolv	Invacare Lift Chair	StandEx
Manufacturer	Altimate Medical	Invacare Corporation	Altimate Medical
510(k) Number	TBD	K002171	K885343
Classification/Product Code	890.3110 / INO	890.3110 / INO	890.5370 / ION
Date Cleared	TBD	August 10, 2000	May 1, 1989
Class	Class II	Class II	Class I
Intended Use	To assist persons who have difficulty rising from a seated position to a standing position	To assist persons who have difficulty rising from a seated position to a standing position	To assist persons to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity.
Basic Construction	Steel Tubing / Plastic / Vinyl	Steel Tubing/Wood/Fabric	Steel Tubing / Plastic / Vinyl
Energy Requirements	Standard: Manual pump action Electrical option: 24 Volt Battery (2)	AC-Power converted to low voltage DC	Manual pump action
Weight Capacity	280 lbs.	350 lbs.	300 lbs.
Mechanical Action	Standard: hydraulic oil cylinder Electrical option: DC linear mechanical worm drive	AC linear mechanical worm drive	Hydraulic oil cylinder

The EasyStand Evolv is comparable to the StandEx device 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 (the Glider model) remains the same between the two devices. The difference between the two devices is the addition of the power lift feature. This power lift feature is comparable to the lift feature in the Invacare Lift Chair in that they both use an electrically powered, low voltage DC, linear mechanical worm drive actuated via a hand held pendant to adjust the seat. Both devices also have the same intended use. The differences between the EasyStand Evolv and the Invacare Lift Chair are that the main electrical power input needed to operate the actuators comes from a battery for the EasyStand Evolv, but for the Invacare Lift Chair, it comes from AC power converted to low voltage DC power; the fact that the EasyStand Evolv seat is covered with Dartex (a polyurethane transfer coating on weft knitted fabric) and the Invacare Lift Chair has a fabric upholstered seat; that the Invacare Lift Chair offers no method of exercise; and that the EasyStand Evolv supports the user to allow for passive standing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2006

Ivacare Corporation
% Mr. Ronald Clines
One Invacare Way
Elyria, Ohio 44035

Re: K062402
Trade/Device Name: EasyStand Evolv
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO
Dated: August 15, 2006
Received: August 17, 2006

Dear Mr. Clines:

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

Sincerely yours,

Mark N. Melkerson
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):

Device Name: EasyStand Evolv

Indications for Use: To assist persons who have difficulty rising from a seated position to a standing position.

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)

Barbara Ouellette

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

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