

5 SECTION 5: 510(K) SUMMARY

510(k) Applicant:

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JAN 15 2008

Date Prepared:

October 8, 2007

Trade Name of Device:

G-Trainer™

Common Name:

Treadmill Unweighing System

Classification Name:

Powered Exerciser (21 CFR 890.5380, Product Code BXB)

Predicate Devices:

Biodex Medical Systems, Inc. (Registration #: 2431314) Gait Training System: Two devices comprise the system, the Gait Trainer 2 treadmill and the Unweighing System. Both components are listed in the FDA Device Listing Database under the manufacturer's name as exempt, Class I devices.

Woodway USA Inc. (Registration #:2133817): ProLift 360, one device, comprised of two components, the Woodway treadmill and the ProLift Unweighing System. The Unweighing system is manufactured by Pneumex, Inc (Registration #: 3032760) and sold to Woodway for incorporation in to the ProLift. Both components are listed in the FDA Device Listing Database under their respective manufacturer's names as exempt, Class I devices. Woodway previously submitted a premarket notification (K962358) to the FDA for the treadmill and the FDA found it to be exempt from premarket notification requirements.

Device Description:

The G-Trainer is designed to provide an adjustable weight support while the user exercises on the incorporated treadmill. The G-trainer is comprised of a standard exercise treadmill with an integrated unweighing component that can effectively reduce

the body weight of an individual while they exercise. A bag that looks much like a small tent is placed over the running surface of the treadmill and sealed in such a manner that an electric blower can inflate the bag. The subject wears a special pair of shorts that zip into the top and center of the bag much like the skirt used on a kayak. The subject zips into the bag and stands on the surface of the treadmill. Using a touch screen control panel, the subject is able to increase or decrease the pressure in the bag. The pressure in the bag provides weight support for the user. By this method, the effective weight of the subject on the treadmill surface can be precisely controlled while they exercise.

The G-Trainer is comprised of a base frame, a treadmill, an upper support frame, the inflatable bag, a pressure source and regulation system, control electronics and a control console.

Intended Use:

The G-Trainer is intended to reduce the load on the lower limbs of an exercising individual, allowing strengthening and conditioning following injury or recovery from corrective surgery. The system may also be used in the rehabilitation of gait. Individuals with lower limb orthopedic problems are expected to be the primary users of the system. Secondly, patients suffering from neurologic problems would be expected to use the system. System operators will be trained medical practitioners operating from clinics, hospitals and research facilities. These applications are consistent with the application and use of the predicate devices.

Summary of Technological Characteristics Compared with the Predicate Devices:

The treadmills used in the G-Trainer and predicate devices are substantially equivalent. All treadmills allow for the adjustment of speed and grade over a similar range of values. Each treadmill has a safety switch mechanism in the event of a fall. The G-Trainer has an additional support structure that surrounds the patient. In the event of a fall, the structure can be used by the patient for support, much like parallel bars are used to support ambulation.

The unweighting mechanism used in the G-Trainer differs technologically from the method used in the predicate devices. The submission device uses a pressurized bag to provide a counterforce to the subject's body weight, reducing their effective weight on the treadmill surface. By adjusting the pressure in the bag, the effective weight of the individual bearing on the surface of the treadmill can be changed. The predicate devices reduce effective body weight by suspending the individual over the treadmill using a cable and pulley system connected to a harness worn by the subject. By changing the tension in the cable, the weight of the individual bearing on the running surface can be adjusted.

Non-Clinical Performance Data:

The results of verification testing indicate the G-Trainer to be highly accurate in adjusting the effective body weight of an exercising subject. Healthy subjects were asked to stand on a calibrated scale placed on the treadmill surface while their effective body weight was adjusted. A highly correlated, linear relationship between %body weight and measured body weight could be demonstrated. The results of this study indicate the G-Trainer to be as effective as the predicate devices in adjusting effective body weight.

Clinical Performance Data

The G-Trainer is a commercialized version of an unweighting device conceived and realized at the NASA Ames Research Center in Mountain View, California. The original intention was to build a machine that could simulate gravity in space as a counter-measure to the deleterious physiologic effects of a low gravity environment. Instead of positive pressure to unweight, a vacuum was applied to increase extremity loading.

Dr. Robert Whalen, one of the inventors, soon realized there may be a clinical application using positive pressure and so contacted the Veterans Administration Rehabilitation Research and Development Center in Palo Alto, California. Their collaboration produced three clinical studies with what could be considered to be G-Trainer prototypes.

The first study demonstrated the feasibility of using positive pressure and an inflatable bag to unweight the individual. Eight healthy male subjects from 29 to 52 years of age stood on a force plate placed within an inflatable bag. The bag was sealed at the waist. A computerized servo valve system was used to control the pressure in the bag. The results demonstrated the effectiveness of using positive pressure and an inflated bag to reduce ground reaction force. Changes in heart rate and blood pressure were of the same magnitude as the change seen when moving from a standing to a supine position.

For the second study a larger bag was fabricated, allowing the placement of a treadmill within the bag. The cardiopulmonary response of nine subjects with stable cardiovascular or respiratory disease was studied at pressures causing 25%, 50% and 75% reduction in body weight, as well as no reduction. No significant difference in cardiovascular response was seen between full body weight and unweighted (75% reduction) exercise. The authors concluded that walking with air pressure support appeared to be safe for individuals with stable cardiovascular conditions.

Ten healthy individuals were studied in a third investigation. They exercised over a range of 0-75% body weight reduction. Ground reaction force was measured and compared to the exercise with no support. A linear relationship was found between ground reaction force and % body weight reduction.

The conclusion to be drawn from the Palo Alto Veterans Administration studies is that the inflated bag technology is very effective at reducing ground reaction force and the impact on the cardiovascular response to exercise over the range of pressures used seems to be nominal.

The co-inventor of the NASA technology, Dr. Alan Hargens, now studies the use of lower body positive pressure in his laboratory at the University of California, San Diego. He uses a treadmill encased in a rigid plastic cube rather than an inflated bag. The cube surrounds the waist with a flexible seal. Two studies are cited from his laboratory.

In the first investigation, 15 patients that had undergone ACL reconstruction or arthroscopic meniscectomy were exercised at 60% and 20% of their normal body weight. Reduction in ground reaction force showed good correlation with the reduction in body weight. Gait and EMG activity were largely unaffected except at 20% of body weight. Pain while exercising was significantly reduced in the ACL patients. The authors concluded that lower body positive pressure exercise is effective at reducing ground reaction forces, while facilitating gait postoperatively.

In a second study, 9 subjects were studied for cardiovascular response to exercise at 20 and 60% of body weight. Six were studied for gait changes at reduced body weight. The authors concluded that neither cardiovascular parameters nor gait characteristics change

significantly with lower body positive pressure exercise. They suggest that lower body positive pressure exercise is a potentially new and safe rehabilitation tool for patients that reduce loads on lower body musculoskeletal structures while preserving gait mechanics.

A sixth study was performed at the University of Colorado, Department of Integrative Biology. Alter-G provided the bag and control technology while the researchers used their own treadmill. A stipend was paid to one of the researchers to cover their salary. Ten healthy recreational runners were studied to determine the relationship between ground reaction force and unweighting. A second goal was to determine the relationship between running speed, degree of unweighting, ground reaction force and metabolic demand. Ground reaction force was observed to decrease linearly with increasing weight support. Running at faster speeds with weight support produced the same metabolic demand as running at slower speeds without support. They found gait kinematics to be only marginally effected at the lower body weights.

A seventh Device Design Validation Trial consisted of placing a G-Trainer prototype at a physical therapy clinic, Ergo-Rehab, of Fremont, CA. The goal was to validate both hardware and software function in a clinical setting. The clinic received the use of the G-Trainer, but was not paid for their advice or reporting. Over an 18 month period, some 470 clients exercised on the G-Trainer prototype. Three hundred seventy five clients were rehabilitated for a range of orthopedic problems, while 95 received general cardiovascular conditioning. The clinic provided Alter-G a monthly spreadsheet report of patient use, pathologies rehabilitated and comments regarding the function of the machine. The clinic reported no adverse incidents while using the G-Trainer and concluded it to be a safe and effective tool in the clinical setting.

The evidence from this range of studies clearly indicates that air pressure differential technology as used in the G-Trainer is highly effective at reducing ground reaction force, and therefore, impact force on the lower extremity in exercising individuals. No adverse events were reported in more than 500 individuals cited in these studies, testament to the safety of the G-Trainer and the use of lower body positive pressure as a means of unweighting. Clinical experience clearly indicates the utility of the G-Trainer in the rehabilitation of a wide variety of orthopedic patients.

Substantial Equivalence Conclusion/Summary:

The G-Trainer has the same intended use as the predicate devices. The treadmills used in both the predicate and G-Trainer devices have the same performance and safety characteristics. The unweighting system used in the G-Trainer, although technologically different from the predicate devices, has been demonstrated through verification and validation testing, as well as clinical experience, to be as effective at reducing effective body weight as those systems used by the predicate devices. Clinical experience in 470 patients indicates the G-Trainer to be a safe and effective rehabilitation tool for a wide variety of lower extremity orthopedic problems. There are no substantially different safety issues introduced by the use of this new unweighting technology. Therefore, we believe that the G-Trainer is substantially equivalent to its predicate devices without raising new safety or effectiveness issues.



JAN 25 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alter-G, Inc
% Mr. Glen Mangseth
1090A O'Brien Drive
Menlo Park, CA 94025

Re: K072887
Trade/Device Name: G-Trainer
Regulation Number: 21 CFR 890.5380
Regulation Name: Powered exerciser equipment
Regulatory Class: Class I
Product Code: BXB
Dated: December 6, 2007
Received: December 7, 2007

Dear Mr. Mangseth:

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.

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

4 SECTION 4: INDICATIONS FOR USE510(k) Number (if known): K072887

Device Name: Alter-G G-Trainer

Indications for Use:

The Alter-G G-Trainer is indicated for use in the following conditions:

Aerobic conditioning
 Weight control and reduction
 Sport specific conditioning programs
 Gait training in neurologic patients
 Strengthening and conditioning in older patients
 Rehabilitation following injury or surgery of the lower extremity
 Rehabilitation following injury or surgery of the hip, knee, ankle or foot.
 Rehabilitation after total joint replacement

The G-Trainer is to be operated by a clinician, trained assistant or athletic trainer at a clinical or conditioning facility in an adult or young adult population at least 5'4" in stature.

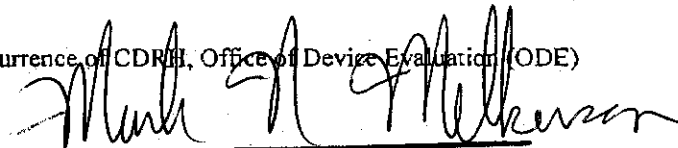
Prescription Use X
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

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Concurrence of CDREH, Office of Device Evaluation (ODE)



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

510(k) Number K072887