MAR 1 - 2005

K033646

Polar HealthFirst

510(k) Summary

Applicant:
Polar HealthFirst Corporation
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Albuquerque, New Mexico 87113
Phone (505) 344-1400
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Point of Contact:
Mr. Jay Skolnik, P.E.

Prepared By:
Skolnik Engineering
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Date Prepared:
December 23, 2004

Trade Name:
TriFIT 700M

Common Name:
Physical Fitness Assessment System

Classification Name:
Computer, Diagnostic, Pre-Programmed, Single-Function

Equivalent Legally Marketed Device: TriFIT 700M is similar in function to the Microfit fitness evaluation system made by Microfit, Inc. in Mountain View, CA.

Description of Device: The TriFIT 700M consists of the following components:

1. A standard desktop computer to include the monitor, keyboard, mouse, and printer
2. Platform weight scale
3. Strength measuring handle
4. Flexibility tester
5. Skin-fold caliper
6. Heart rate monitor

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These components all attach to an interface box. This interface box attaches to the computer via a serial cable. Some components are optional.

Intended Use: The TriFIT 700M is used to measure an individual's physical fitness level. Measurements include body weight, biceps strength, flexibility, skin-fold thickness (to estimate percentage body fat), and heart rate.

Technological Characteristics: The TriFIT 700M is substantially equivalent to the Microfit Fitness Evaluation System. The systems are both operated by a PC, and consist of a bike and ancillary components for measurements that are basically identical.

Comparison Table		
	Microfit	**TriFIT 700M**
Intended Use		
Physical fitness assessment device to be used on apparently healthy population	*	*
Interactive Assessments		
Body Weight	*	*
Biceps Strength	*	*
Sit and Reach Flexibility Test	*	*
Skin-fold Calipers for Body Composition	*	*
Bike with Heart Rate Receiver and RPM pickup	*	*
Data Entry/Software		
Demographic Information (address, phone, email, etc.)	*	*
Health Risk Questionnaires	*	*
Fields tests-manual keyboard entry	*	*
Exercise Programming	*	*

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 - 2005

Polar HealthFirst Corporation
c/o Mr. Jay Skolnik, PE
Skolnik Engineering
13170-B Central Ave. SE
Suite 115
Albuquerque, NM 87123

Re: K033646
Trade Name: TriFIT 700M
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate and alarm)
Regulatory Class: II (two)
Product Code: DRT
Dated: December 23, 2004
Received: December 27, 2004

Dear Mr. Skolnik:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K033646

Device Name: TriFIT 700M

Indications For Use:

The TriFIT 700M is a physical fitness assessment device which can be used in both medical and non-medical settings. It is used for individuals to test and to measure their physical fitness levels. The assessment includes body weight, biceps strength, flexibility, skin-fold thickness (to estimate percentage body fat), and heart rate.

Prescription Use: No
(Part 21 CFR 801 Subpart D)

And/Or

Over-The-Counter Use: Yes
(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 Cardiovascular Devices
510(k) Number K033646