K052522
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DEC 13 2005

SUMMARY

Stayhealthy Inc.
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Contact Mr. John Collins

Summary prepared September 8th, 2005.

Section 6.1 Stayhealthy BC1 and Stayhealthy/Fitness Expert BC2, Body composition analyzer 510K submission.

SUMMARY

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

Trade name: Stayhealthy BC1 and Stayhealthy/Fitness Expert Fitness Expert BC2, Body Composition Analyzer. Stayhealthy CT1 and Stayhealthy/Fitness Expert CT2
Common Name: Body composition analyzer/body fat analyzer and calorie tracker.
Classification: II
Name: ANALYZER, BODY COMPOSITION.
21 CFR part 870.2770

Description of applicant devices:
The Stayhealthy BC1 and Stayhealthy/ Fitness expert BC2, Body Composition Analyzer is a computer-operated and web enabled body composition analyzer that utilizes BIA (bioelectrical impedance analysis) to determine body fat percent and lean body mass percent. Both devices are about 10 inches across. The BC1 has an oval shape and is about 3 inches thick. The BC2 has an almost square shape with rounded corners. Both devices are made of slate grey plastics with polished metal inserts that are held by the hands to emit and receive signals to and from the body. The BC1 has an RS232 output socket and the BC2 has a USB output socket. Both devices have a dock where the calorie tracker is docked to upload its data. The CT1 and CT2 are both about 2 by 3 inches and made of slate gray plastics with a single display window and a docking port. They can be attached to clothes on the body via a clip on the back.

Intended Uses of the Applicant Device:
The BC1 and the BC2 are used as body fat analyzers that estimate the body fat and lean body mass with use of BIA (bioelectrical impedance analysis). The CT1 and the CT2 devices that are sold as companion devices with the BC1 and BC2 are used to track the number of calories used by the client. (Based on selected motion detection).
Predicate device(s);
Omron Body Fat Analyzer Model HBF-306
K011652
Scientific Concepts and Significant Performance Characteristics

	Body fat analyzer Model HBF-306 Omron Healthcare.	**Body composition Analyzer Model BC1 And BC2 Stayhealthy and Stayhealthy/ Fitness Expert.**
Intended use:	**A handheld device that Estimates body fat Composition using BIA and outputs percent fat on a Digital display.**	**A handheld device connected to a computer that estimates body fat composition using BIA and outputs percent fat on a computer display**
Product Description:	**Body composition analyzer**	**Body composition analyzer that**

	that utilizes "hand to hand" BIA technology to determine internal body composition	Utilizes "hand to hand" BIA technology to determine internal body composition
Analytical Method/ Measurement:	Hand to Hand BIA In House BIA and DEXA methods	Hand to Hand BIA In House and Third party BIA and Hydrostatic methods

Other technical data: The BC1/BC2 devices have been tested for conformity to industry standard safety tests for medical electrical equipment. These included EN 60601-1, EN 60601-1-1, En 60601-1-2, EN 61000-3-2, EN 61000-3-3, and CAN/ CSA C22.2 No 601.1-M90.

Clinical Data. Stayhealthy commissioned the University of East Tennessee to perform a clinical trial comparing the accuracy of the BC1 to the "gold Standard" of hydrostatic immersion for estimation of body fat percent. This study included 72 subjects, both men and women, ages 18 to 45, and lean to overweight. The results showed a tight correlation between the two methods of measurement over the age range and the weight range used. There was less than a 0.5% variation in three BC1 measurements made on each individual. There was no significant difference between the total body composition values for the hydrostatic method compared to the BC1 (BIA method) (P value 0.05).

Conclusion. Since the core technology and the algorithms used in the BC1 model and the BC2 are the same and both have been tested for safety we can conclude that both devices are safe, effective and perform as good as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2005

Mr. John Collins
CEO
Stayhealthy, Inc.
300 Elfwood Drive
MONROVIA CA 91016

Re: K052522
Trade/Device Name: Stayhealthy Body Composition Analyzer (BC1)
Stayhealthy/Fitness Expert Body Composition Analyzer (BC2)
Stayhealthy Calorie Tracker (CT1)
Stayhealthy/Fitness Expert Calorie Tracker (CT2)
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: September 13, 2005
Received: September 14, 2005

Dear Mr. Collins:

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052522

Device Name: Stayhealthy Body Composition Analyzer (BC1) and Stayhealthy/Fitness Expert Body Composition Analyzer (BC2)
The Stayhealthy Calorie Tracker (CT1) and the Stayhealthy/Fitness Expert Calorie Tracker (CT2)

Indications for Use:
The Stayhealthy BC1 and the Stayhealthy/Fitness Expert BC2 devices are used solely to estimate the body fat and lean muscle components of the body using bioelectrical impedance technology.
The Stayhealthy Calorie tracker (CT1) and the Stayhealthy/Fitness Expert Calorie Tracker (CT2) are companion devices and are used solely to determine the calories used by a client when worn for a given period of time.

The BC1 and BC2 can output, via computer driven software the percent body fat of a person. The lean body mass can also be displayed. The devices are intended for use by both men and women who are 18 and older. The CT1 and the CT2 the companion devices can output, via computer driven software the number calories used by a person. The calories used can also be displayed. The BC1, BC2, CT1 and CT2 are not intended to be used to diagnose any known disease.

Prescription Use __N/A_____(Part 21 CFR 801 Subpart D) AND/OR
Over-The-Counter Use ___YES____(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052522