K060504

FEB 6

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SUMMARY OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

Jason Goldberg
IDEAL LIFE INC.
110 Eglinton Avenue West
Suite 303
Toronto, Ontario Canada M4R 1A3

1.2 Official Correspondent

Diane Mandell, Ph.D., RAC
THE WEINBERG GROUP INC.
1220 19th Street N.W., Suite 300
Washington, D.C. 20036
Telephone: 202.730.4130
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1.3 Date of Preparation

February 6, 2006

2 NAME OF THE DEVICES

2.1 Trade/Proprietary Names

IDEAL LIFE BP-MANAGER™, Model BPM 0001;
IDEAL LIFE POD™, Model ILP 0001

2.2 Common/Usual Names

Noninvasive Blood Pressure Measurement System;
Radiofrequency Physiological Signal Transmitter and Receiver

2.3 Classification Information

Classification Name:	System, Measurement, Blood-Pressure, Noninvasive
Classification Regulation:	21 CFR §870.1130
Class:	II
Product Code:	DXN
Panel:	Circulatory System Devices

Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Classification Regulation:	21 CFR §870.2910
Class:	II
Product Code:	DRG
Panel:	Circulatory System Devices

3 PREDICATE DEVICES

1. Omron Automatic Blood Pressure Monitor with Intellisense™, Model HEM-773AC (K021682),
2. IN TOUCH® Diabetes Management Software System, K984527; and
3. Carematix Wellness System, K031840.

4 DESCRIPTION OF THE DEVICES

The IDEAL LIFE BP-MANAGER™ is a single unit software-controlled device with a blood pressure cuff, and operation is automatic. The IDEAL LIFE BP-MANAGER™ can be used alone without any other accessories. Blood pressure and heart rate results are displayed on the screen of the IDEAL LIFE BP-MANAGER™. Up to 70 blood pressure readings are stored in the blood pressure computer processor. The device is not intended for self-diagnosis of disease and it is expected that individuals using the IDEAL LIFE BP-MANAGER™ will consult with a physician for interpretation of results.

If an individual desires automated graphical presentation of their blood pressure and heart rate data, the IDEAL LIFE POD™ may be purchased separately and used with the IDEAL LIFE BP-MANAGER™ as an optional accessory. The IDEAL LIFE POD™ is not required for operation of the IDEAL LIFE BP-MANAGER™. The IDEAL LIFE POD™ is a simple transmitter (i.e., a wireless router) that is intended to transmit data obtained by the IDEAL LIFE BP-MANAGER™ to the internet via common telephone lines from the user's home setting.

5 INDICATIONS FOR USE AND INTENDED USE

The IDEAL LIFE BP-MANAGER™ is a non-invasive blood pressure monitor intended for the measurement of systolic and diastolic blood pressure and heart rate (pulse rate) using the oscillometric technique.

The IDEAL LIFE BP-MANAGER™ should be used in adults (individuals aged 18 and older) in a non-clinical environment such as in the home. The IDEAL LIFE BP-MANAGER™ should not be used on infants or children. The end user of this device should not have common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation. This device makes no interpretation, evaluation, medical judgments or

recommendations for treatment. Clinical judgment and experience are required for interpretation of information. This device is not intended as a substitute for medical care. The IDEAL LIFE POD™ is an optional accessory to the IDEAL LIFE BP-MANAGER™ and is a transmitter that is intended to transmit data obtained by the IDEAL LIFE BP-MANAGER™ to the internet via common telephone lines from the user's home setting.

The IDEAL LIFE POD™ is an optional accessory designed to assist in the management of user information. This device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required to check or interpret information transmitted. This device is not intended as a substitute for medical care.

6 SUBSTANTIAL EQUIVALENCE

The IDEAL LIFE BP-MANAGER™ (Model No. BPM 0001) is substantially equivalent to the K021682, Omron Automatic Blood Pressure Monitor with Intellisense™, Model HEM-773AC. These devices have similar intended uses and technology comparisons.

The IDEAL LIFE POD™ (Model No. ILP 0001) is substantially equivalent to two predicate devices: K984527, IN TOUCH® Diabetes Management Software System (similar in intended use); and K031840, Carematix Wellness System (similar in technological comparison). Any differences between these devices and the IDEAL LIFE devices do not affect safety and effectiveness of the IDEAL LIFE devices, as demonstrated through bench and clinical testing of the IDEAL LIFE devices.

7 PERFORMANCE TESTING

This 510(k) provided performance testing data in accordance with the guidance document entitled "Non-Invasive Blood Pressure (NIBP) Monitor Guidance" dated March 10, 1997. These performance data included electromagnetic compatibility, electrical testing, performance testing in human volunteers, as well as other performance tests. Results of these tests confirm the appropriate performance of both the IDEAL LIFE BP-MANAGER™ and the IDEAL LIFE POD™, and the substantial equivalence of these devices to the predicates.

8 CONCLUSIONS

This 510(k) submission demonstrates that the IDEAL LIFE BP-MANAGER™ and the IDEAL LIFE POD™ are substantially equivalent to the three predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2006

Ideal Life, Inc.
c/o Diane Mandell, Ph.D., RAC
The Weinberg Group, Inc.
1220 19th Street N. W., Suite 300
Washington, DC 20036

Re: K060504
Trade Name: IDEAL LIFE BP-MANAGER™, Model BPM 0001 and
IDEAL LIFE POD™, Model ILP 0001
Regulation Number: 21 CFR 870.1130 and 21 CFR 870.2910
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN and DRG
Dated: February 06, 2006
Received: February 27, 2006

Dear Dr. Mandell:

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,

B Zuckerman for

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

Enclosure

K060504

Attachment 1b

510(k) Number (if known): K060504
Device Name: IDEAL LIFE BP-MANAGER™ and IDEAL LIFE POD™

Indications for Use:

The IDEAL LIFE BP-MANAGER™ is a non-invasive blood pressure monitor intended for the measurement of systolic and diastolic blood pressure and heart rate (pulse rate) using the oscillometric technique.
The IDEAL LIFE BP-MANAGER™ should be used in adults (individuals aged 18 and older) in a non-clinical environment such as in the home. The IDEAL LIFE BPMANAGER ™ should not be used on infants or children. The end user of this device should not have common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation. This device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required for interpretation of information. This device is not intended as a substitute for medical care.

The IDEAL LIFE POD™ is an optional accessory to the IDEAL LIFE BPMANAGER ™ and is a transmitter that is intended to transmit data obtained by the IDEAL LIFE BP-MANAGER™ to the internet via common telephone lines from the user's home setting. The IDEAL LIFE POD™ is an optional accessory designed to assist in the management of user information. This device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required to check or interpret information transmitted. This device is not intended as a substitute for medical care.

(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 K060504

Prescription Use ___ OR Over-the-Counter Use _X_
(Per 21CFR801.109)