HealthGuard International Inc.
Special 510(k)
Model 2400 Automatic Blood Pressure Measurement System
510(K) Summary

December 11, 2003

(1) Submitter Information

Name: HealthGuard International Inc..

Address: 255 North Washhington St.
Rockville, MD 20850

Telephone Number: 301-279-7300

Contact Person: Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703

Date Prepared: February 20, 2004

(2) Name of Device:

Trade Name: Lifeclinic 2400
Common Name: Automated Blood Pressure Monitor.
Classification Name: System, measurement, blood pressure, non-invasive, systolic and/or diastolic, 74JOE, 870.1130

(3) Equivalent legally-marketed devices:

K850893, "BP/Clinic"

(4) Description

The Lifeclinic 2400 is an automated system for measuring blood pressure and pulse rate designed to be used by the general public in stores and other places. It is completely automatic, and measures blood pressure by the oscillometric method. The user is guided by a series of interactive screens and voice instructions.

(5) Intended Use

The Lifeclinic 2400 is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate. It is not a diagnostic device, and only furnishes data so that users can consult their personal physicians.

(6) Technological characteristics

The Lifeclinic 2400 consists of a fixed cuff into which the user inserts an arm. The cuff automatically inflates and then deflates after the user presses a button. The device measures blood pressure using the oscillometric method.

(b) Performance data

(1) Non-clinical tests

The unit meets all required AAMI tests for such devices.

(2) Clinical tests

Not required

(3) Conclusions

The Lifeclinic 2400 is equivalent in safety and efficacy to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2004

Lifeclinic International, Inc.
c/o Mr. George H. Myers
Medsys, Inc.
377 Route 17 S.
Hasbrouck Heights, NJ 07604

Re: K040562
Trade Name: Lifeclinic LC500
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: August 19, 2004
Received: August 20, 2004

Dear Mr. Myers:

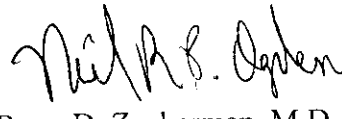
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K040562

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510(k) Number (if known): K040562

Device Name: Lifeclinic LC500

Indications for Use:

The Lifeclinic LC500 is indicated for the measurement of blood pressure and heart rate by members of the general public. The device does not perform any diagnoses; it only provides pressure and rate data to the users, who are advised to consult a physician.

Prescription Use _____ **OR** **Over-the-Counter Use** X
(Per 21 CFR 810.109)

(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 K040562