K050929

SECTION E SUMMARY

MAY 2 0 2005

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Palaistra Systems Inc. summary for the Hermes System.

SUBMITTER'S NAME:	Palaistra Systems Inc.
ADDRESS:	2530 Meridian Parkway, Suite 300
CONTACT PERSON:	Daniel R. Plonski
CONTACT PERSON TITLE	Director of Product Management
TELEPHONE NUMBER:	(919) 806-4323
FAX NUMBER:	(919) 806-4802
DATE OF SUBMISSION:	March 25, 2005

1 Identification of device

Proprietary Name: The Hermes System

Common Name: Physiological Transmitter and Receiver

Classification Status: Class II per regulations 870.2910

Product Codes: DRG

2 Equivalent devices

Palaistra Systems Inc. believes the Hermes System is substantially equivalent to the following legally marketed devices:

- Telehealth Gateway: K041816 (DRG)
- Carematix: K040966 (DXN and DRG)

3 Description of the device

The Hermes System is an accessory device that collects data from a range of supported measurement devices. The data is collected and sent using standard wireless technologies and maintained on an associated database server located within the healthcare facility. Based on patient specific parameters set by the healthcare provider, educational and motivational messages are returned to the patient. Hermes is used by the patient to collect data from one or more off-the-

shelf measurement devices. Hermes currently supports a glucometer, a non-invasive blood pressure cuff and a weight scale.

Hermes is a software system composed of two components, a Collector module and a Server module. The Collector module is a software program that runs on a cell phone and provides the data collection, transmission and message display capabilities. The Server module is a software program that runs on standard web server hardware. The Server module receives the data sent to it by the Collector module and provides the set-up, data management, and message delivery capabilities.

Hermes messages remind the user of good health habits such as taking all prescribed measurements and maintaining a healthy lifestyle. Hermes can send email to the patient's doctor and/or guardian if good habits are not maintained.

4 *Intended use*

The Hermes System is intended to be used by out-of-hospital patients as a means to collect and transmit medical measurements (such as blood glucose level, weight, and blood pressure) to their healthcare provider and to receive returned educational and motivational messages to help them better understand and manage their chronic condition. The Hermes System is to be used only upon prescription of a licensed physician or other authorized healthcare provider.

The Hermes System is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.

Hermes is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

5 *Technological characteristics, comparison to predicate device.*

The Hermes System provides equivalent functionality as the following legally marketed devices:

- Telehealth Gateway: K041816 (DRG)
- Carematix: K040966 (DXN and DRG)

Three characteristics differentiate The Hermes System from the predicate devices:

1. *Data Collection Platform* – The Hermes Collector runs on a cell phone while both of the predicate devices run on proprietary hardware.

2. *Communications technology* – Hermes uses the Bluetooth protocol to communicate with the off-the-shelf measurement devices. The Telehealth Gateway also uses Bluetooth. Carematix uses a non-Bluetooth RF protocol. Hermes uses secure wireless network technology to send data to the healthcare facility server. Both of the predicate devices use a standard phone line.

3. *Patient Feedback Messages* – Hermes provides feedback messages to patients to reinforce good health habits. The Telehealth device does not provide feedback and the Carematix device provides some capability to send email messages to the patient.

6 *Discussion of functional and safety testing.*

An extensive collection of tests has been conducted and successfully completed, including usability and pilot studies, software unit, integration, system and load/performance testing and document verification.

7 *Conclusion*

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Palaistra Systems Inc. that the Hermes System is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2005

Palaistra Systems, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, Inc.
1394 25th Street NW
Buffalo, MN 55313

Re: K050929
Trade Name: The Hermes System
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiologic Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: May 5, 2005
Received: May 6, 2005

Dear Mr. Job:

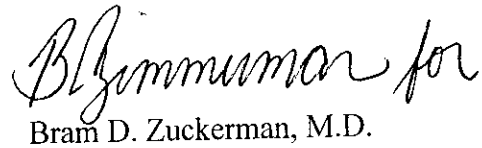
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 may be obtained 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

Indications for Use

510(k) Number (if known): K050929

Device Name: The Hermes System

Indications For Use:

The Hermes System is intended to be used by out-of-hospital patients as a means to collect and transmit medical measurements (such as blood glucose level, weight, and blood pressure) to their healthcare provider and to receive returned educational and motivational messages to help them better understand and manage their chronic condition. The Hermes System is to be used only upon prescription of a licensed physician or other authorized healthcare provider.

The Hermes System is an accessory device that collects data from a range of supported monitoring devices. The data is collected and sent using standard wireless technologies and maintained on an associated database server located within the healthcare facility. Based on patient specific parameters set by the healthcare provider, educational and motivational messages are returned to the patient.

Continued on next page.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K050929

Hermes is a software system composed of two components, a Collector module and a Server module. The Collector module is a software program that runs on a cell phone and provides the data collection, transmission and message display capabilities. The Server module is a software program that runs on standard web server hardware. The Server module receives the data sent to it by the Collector module and provides the set-up, data management, and message delivery capabilities.

Hermes messages remind the user of good health habits such as taking all prescribed measurements and maintaining a healthy lifestyle. Hermes can send email to the patient's doctor and/or guardian if good habits are not maintained.

The Hermes System is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.

Hermes is not intended to provide automated treatment decisions, nor to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.