

**PREMARKET NOTIFICATION 510(k) SUMMARY**  
**As required by §807.92**

**Device Name – as required by 807.92(a)(2):**

510(k) Number: **K062377**

Trade Name: **MedApps™ Remote Patient Monitoring System**

Common/Classification Name: **Transmitters and Receivers, Physiological Signal, Radiofrequency**

Classification Regulation: **870.2910**

Device Class: **Class II**

Product Code (Procode): **DRG**

Premarket Notification submitter:  
Company Name: **MedApps, Inc.**  
Company Address: **7975 North Hayden Road,  
Suite B-200, Scottsdale, AZ 85258**

Contact: **Kent E. Dicks, President and CEO**

Preparation Date: August 14, 2006  
Revision Date: April 3, 2007

**A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)**

Legally marketed predicate device are:

K061328 Think Positive (t+) Diabetes Management System  
K050929 The Hermes System

The submitted device is intended to be an accessory device to the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System (K024194/K043197).

**B. DEVICE DESCRIPTION – as required by 807.92(a)(4)**

The MedApps Wellness System ("System") is designed to be used by patients to send their data from the LifeScan OneTouch Ultra glucometer to a central server for subsequent storage and display.

The System is comprised of a "Hub" (cell phone software) and the MedApps Engine, which runs on a central server.

The Hub is a software program that runs on a cell phone and takes in data from the OneTouch Ultra and then transmits it to the central server for storage and processing.

The MedApps Engine is a software program that runs on a common Web / Internet secure server platform. The MedApps Engine picks up the stored data sent to it by the Hub and through a set of business rules set by the healthcare providers, determines if a follow-up Interactive Voice Response (IVR) call is required to be made to the patient to collect additional Behavioral information from the patient.

Once all the data is collected, then it is stored in a repository for access by the healthcare provider.

The Hub will utilize the OneTouch Ultra integrated Short-range low power wireless transmission (Bluetooth V1.2) or a FDA approved accessory to the medical devices that transmits the medical device data via Bluetooth to a compatible cellular telephone, such as the Nokia 6620, or other /compatible cellular phones.

**C. INTENDED USE - as required by 807.92(a)(5)**

The MedApps Wellness System is intended for use in non-clinical settings to collect and transmit historical data to healthcare professionals to help support effective management of patients.

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

**D. INDICATIONS FOR USE**

The MedApps Wellness System model D-PAL acts as an accessory to FDA cleared devices, which collects and transmits stored patient data via wireless connections from medical devices to a cellular phone (Hub) and forwards to a central server for review of historical data about a patient over time to benefit the Healthcare Practitioner.

The following medical devices and measuring systems are fully validated for this intended use at this time:

- LifeScan OneTouch ® Ultra® Blood Glucose Monitoring System (K024194 / K043197)
- Polytel PWR-08-03 Remote Module (K070559 pending clearance)

The MedApps Wellness System 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.

The MedApps Wellness System is not intended for emergency calls, and may not be used for transmission or indication of any real-time alarms or time-critical data.

Clinical judgment and experience are required to check and interpret the measurements collected and transmitted.

This device is not for use in systems which substitute for medical care.

This device is not intended for patients requiring direct medical supervision or emergency intervention.

**E. LEVEL OF CONCERN – as requested by recent FDA guidance**

The FDA guidance document "**Guidance For The Content of Premarket Submissions For Software Contained In Medical Devices,**" May 11, 2005, clearly identifies that all manufacturers of software devices are responsible for determining a **Level of Concern** for their device(s).

**MedApps, Inc.** believes that this device, because of its functional characteristics and intended uses, has a **MODERATE LEVEL OF CONCERN**. See Exhibit 4, Level of Concern.

**F. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)**

Feature	Think Positive K061328	The Hermes K050929	MedApps (Submission Device)
<b>Indications of Use</b>	Enables healthcare providers to monitor and manage chronic conditions of patients remotely	Same	Same
<b>Intended Use</b>	Telemedicine System	Same	Same
<b>Intended Users</b>	Home users and Healthcare providers	Same	Same
<b>Site of Use</b>	Home, Clinic	Same	Same
<b>Data Collection Software</b>	Think Positive Proprietary Software	The Hermes Proprietary Software	MedApps Proprietary Software
<b>Data Collection Software Functionality</b>	Transmit data from Sensor devices to Central Database	Same	Same
<b>Communication method of hub with Central Server</b>	Via Cellular Phone	Same	Same

<b>Feature</b>	<b>Think Positive K061328</b>	<b>The Hermes K050929</b>	<b>MedApps (Submission Device)</b>
<b>Types of sensors which can be interfaced (wired or wirelessly) to receiver hub</b>	Glucose Levels	Same	Same
<b>Implementation method of collecting data from sensors</b>	Short range radio system using Bluetooth and Cellular technology	Same	Same
<b>Sensor Software</b>	Sensor Software unchanged	Same	Same
<b>Connectivity</b>	Short range radio system using Bluetooth and Cellular technology	Same	Same
<b>Communication method of hub with devices</b>	Short range radio system using Bluetooth and Cellular technology	Same	Same
<b>Communications Protocol</b>	Bluetooth V1.2	Same	Same
<b>Communication Frequency</b>	2.402 to 2.480 GHz	Same	Same
<b>Power Source</b>	Wall power plug for hub (120 VAC/50-60) and batteries in devices	Same	Same
<b>Display</b>	On devices and hub, and monitors connected to central server	Same	Same
<b>Communication with Patients</b>	On screen display	Same	On screen display of Readings and Interactive Voice Response (IVR)

**G. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)**

**Non-Clinical Testing**

The submitted device has undergone significant verification and validation testing. Alpha validation testing included testing of all executable code and functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface, documentation or user SOP.

Alpha validation activities included exhaustive validation scripts of all Software Design Specifications (SDS), which was summarized and discussed to provide a preliminary record of performance data. Additionally, the submitter duplicated the operational environment of a sophisticated user and provided the complete record of those executed scripts as operational performance data. The output of these two performance data records documents that **MedApps Wellness System** met its required requirements and design specifications as intended.

**H. SUBSTANTIAL EQUIVALENCE SUMMARY**

The submitted device, **MedApps Wellness System**, has the same indications for use as the predicate devices, *Think Positive (t+) Diabetes Management System and The Hermes System*.

**I. CONCLUSIONS**

The performance and usability testing and validation studies document that **MedApps Wellness System** is substantially equivalent to the predicate *Think Positive (t+) Diabetes Management System and The Hermes System*.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MedApps, Inc.  
c/o Mr. Kent E. Dicks  
President/CEO  
7975 North Hayden Road, Suite B-200  
Scottsdale, AZ 85258

**JUL - 3 2007**

Re: k062377  
Trade/Device Name: MedApps™ Remote Patient Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Code: NBW  
Dated: June 26, 2007  
Received: June 27, 2007

Dear Mr. Dicks:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): k062377

Device Name: MedApps™ Remote Patient Monitoring System

### Indication For Use:

The MedApps Remote Patient Monitoring System model d-PAL acts as an accessory to FDA cleared devices, which collects and transmits stored patient data via wireless connections from medical devices to a cellular phone (Hub) and forwards to a central server for review of historical data about a patient over time to benefit the Healthcare Practitioner.

The following medical devices and measuring systems are fully validated for this intended use at this time:

- LifeScan OneTouch® Ultra® Blood Glucose Monitoring System (k024194/k043197)
- Polytel PWR-08-03 Remote Module (k070559)

The MedApps Remote Patient Monitoring System 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.

The MedApps Remote Patient Monitoring System is not intended for emergency calls, and may not be used for transmission or indication of any real-time alarms or time-critical data. Clinical judgment and experience are required to check and interpret the measurements collected and transmitted. This device is not for use in systems which substitute for medical care. This device is not intended for patients requiring direct medical supervision or emergency intervention.

Prescription Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use  X   
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
\_\_\_\_\_  
Division Sign-Off

**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

    K062377