

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

k062377

B. Purpose for Submission:

Software allowing data transfer from a cell phone to a central server for viewing.

C. Manufacturer and Instrument Name:

MedApps, Inc., MedApps Remote Patient Monitoring System

D. Type of Test or Tests Performed:

This device does not directly test glucose. This is an accessory to previously a cleared glucose monitor (k024194/k043197).

E. System Descriptions:

1. Device Description:

The MedApps Remote Patient Monitoring System (“System”) is designed to be used by patients to send their data from the LifeScan OneTouch Ultra glucose meter 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 (sent via the Polytel device (k070559)) and then transmits it to the central server for storage and processing.

2. Principles of Operation:

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.

3. Modes of Operation:
Wireless data transfer of stored glucose measurements from a cell phone to a central server where the data is accessible via the internet.
4. Specimen Identification:
For an example, see k024194/k043197.
5. Specimen Sampling and Handling:
For an example, see k024194/k043197.
6. Calibration:
For an example, see k024194/k043197.
7. Quality Control:
For an example, see k024194/k043197.
8. Software:
FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
Yes ___X___ or No _____

F. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
2. Classification:
Class II
3. Product code:
NBW
4. Panel:
75 (Clinical Chemistry)

G. Intended Use:

1. Indication(s) 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.

2. Special Conditions for Use Statement(s):
For over-the counter use

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
k061328, Think Positive (t+) Diabetes Management System
k050929, The Hermes System

2. Comparison with Predicate Device:

Feature	Think Positive k061328	The Hermes k050929	MedApps (Submission Device)
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely	Same	Same
Intended Use	Telemedicine System	Same	Same
Intended Users	Home users and Healthcare providers	Same	Same

Site of Use	Home, Clinic	Same	Same
Data Collection Software	Think Positive Proprietary Software	The Hermes Proprietary Software	MedApps Proprietary Software
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same	Same
Communication method of hub with Central Server	Via Cellular Phone	Same	Same
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Glucose Levels	Same	Same
Implementation method of collecting data from sensors	Short range radio system using Bluetooth and Cellular technology	Same	Same
Sensor Software	Sensor Software unchanged	Same	Same
Connectivity	Short range radio system using Bluetooth and Cellular technology	Same	Same
Communication method of hub with devices	Short range radio system using Bluetooth and Cellular technology	Same	Same
Communication s Protocol	Bluetooth V1.2	Same	Same

Communication Frequency	2.402 to 2.480 GHz	Same	Same
Power Source	Wall power plug for hub (120 VAC/50-60) and batteries in devices	Same	Same
Display	On devices and hub, and monitors connected to central server	Same	Same
Communication with Patients	On screen display	Same	On screen display of Readings and Interactive Voice Response (IVR)

I. Special Control/Guidance Document Referenced (if applicable):

- 1) Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005
- 2) Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers, April 19, 2001
- 3) Guidance for Industry – Part 11, Electronic Records; Electronic Signatures – Scope and Application, August 2003
- 4) Design Control Guidance for Medical Device Manufacturers, March 11, 1997
- 5) ISO 9001:2000 – Quality Management Systems – Requirements
- 6) ISO 13485:2003 – Quality Management Systems – Requirements for Medical Devices
- 7) 93/42/EEC – Medical Device Directive
- 8) ISO 14971:2000 Medical Devices – Application of Risk Management to Medical Devices
- 9) ANSI/AAMI HE74: 2001 – Human factors design process for medical devices
- 10) IEC 60601-1 – Medical electrical equipment – Parts 1-8: General requirements for safety

J. Performance Characteristics:

1. Analytical Performance:
 - a. *Accuracy:*
The sponsor validated overall software usage and data transfer functionality. Software usage validation entailed testing each of the software's design

requirements to ensure that they were met. Data transfer was tested by transferring sets of data from the transmitter (phone) to the database and checking that the data was downloaded in its entirety, and that the data points (results) that were transferred from the phone to the database matched the original data taken from the phone. Data transmitted from the glucose meter to the phone was validated in k070559.

For an example of performance of the glucose meter and strips see k024194/k043197.

b. Precision/Reproducibility:

For an example of performance of the glucose meter and strips see k024194/k043197.

c. Linearity:

For an example of performance of the glucose meter and strips see k024194/k043197.

d. Carryover:

For an example of performance of the glucose meter and strips see k024194/k043197.

e. Interfering Substances:

For an example of performance of the glucose meter and strips see k024194/k043197.

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.