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

A. 510(k) Number:
k083263

B. Purpose for Submission:
A 510(k) for a diabetes management program and website using the Polymap Wireless Polytel GMA glucose meter data transmission accessory cleared under k070559

C. Manufacturer and Instrument Name:
Symcare Personalized Health Solutions, Inc
Symcare Diabetes Management Program

D. Type of Test or Tests performed:
Glucose data transmission

E. System Descriptions:
1. Device Description:
    The SymCare Diabetes Management Program (DMP) is an online tool that helps patients to manage their diabetes and communicate their blood glucose readings to their invited healthcare professionals, who they partner with in managing their diabetes. A validated blood glucose meter connected via a Bluetooth accessory, "the Polymap Wireless Polytel Glucose Meter Accessory (GMA)" (k070559), to a validated cellular phone, is used to transmit glucose readings from the glucose meter to the DMP online system, which is accessible by the healthcare provider as well as the patient.

2. Principles of Operation:
    Not applicable

3. Modes of Operation:
    Not applicable

4. Specimen Identification:
    Not applicable

5. Specimen Sampling and Handling:
    Not applicable

6. Calibration:
    Not applicable

7. Quality Control:
   Not Applicable

8. Software:

   The system requirements for the DMP are:

   Operating Systems:
   Windows XP or VISTA Home Premium or better
   Macintosh OS X
   Linux

   Browsers:
   Firefox 2.x/3.x
   Internet Explorer 7 or 8
   Adobe Flash 8 plug in
   Acrobat Reader 5.0 plug in
   Safari

   FDA has reviewed the applicant's Hazard Analysis and software
   Documentation: Yes__X___ or No _____

   The applicant provided software documentation that supports the device was
   designed and developed under good software LifeCycle processes.

F. Regulatory Information:

1. Regulation Section:
   21CFR §862.1345 - Glucose Test System
   21CFR §862.2100 - Calculator/Data Processing Module for Clinical Use

2. Classification:
   Class II, I respectively

3. Product Code:
   NBW, JQP

4. Panel:
   75, Chemistry

G. Intended Use:

1. Indication(s) for Use:

   The SymCare Diabetes Management Program is intended for use in home
   settings to aid people with diabetes and healthcare professionals in the review,
   analysis and evaluation of historical blood glucose test results to support

effective diabetes management. It is intended for use as an accessory to blood glucose meters with data management capabilities. This system is intended for use by people 18 years of age and older. The SymCare Diabetes Management Program is not intended to provide 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.

2. Special Condition for use Statement(s):
    Prescription use

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
    MyCare Team Inc., MCT-Diabetes (k073699)
    e-San Limited, Think Positive Diabetes Management System (k061328)

2. Comparison with Predicate Device

COMPARISON OF THE SYMCARE DMP TO THE MCT-DIABETES and THINK POSITIVE DMS		
SYMCARE DMP (Subject)	**MCT-DIABETES (Predicate K073699)**	**THINK POSITIVE DMS (Predicate K061328)**
The SymCare Diabetes Management Program is intended for use in home settings to aid people with diabetes and healthcare professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data management capabilities. This system is intended for use by people 18 years of age and older. The SymCare Diabetes Management Program is not intended to provide 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 MCT-Diabetes software serves as an interface between the software in personal glucose monitoring devices and a general purpose health management database to assist in the review, analysis and evaluation of blood glucose test results. MCT-Diabetes is designed for home use and professional healthcare settings.	The e-San Bluetooth Cradle is intended to be used by patients at home. It is physically connected to a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and wirelessly sends the signals (via Bluetooth V1.2) to a Bluetooth enable cellular phone such as the Nokia 6230. The e-San Bluetooth Cradle serves as the remote communication link between the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and a cellular telephone. The t+ Diabetes System enables users to store and display data on the cellular phone, and to send data from the cellular telephone to a remote database for storage and display via the internet.

Features	SYMCARE DMP (Subject)	MCT-DIABETES (Predicate K073699)	THINK POSITIVE (t+) DMS (Predicate K061328)
Intended Users	Home users, healthcare providers (including SymCare healthcare professionals)	Home use or clinical assist diabetics, families, and professionals in management of blood glucose support diabetes management	Home users and healthcare providers
Software Use	Single (individual) or multiple user (clinical) settings	Single (individual) or multiple user (clinical) settings	Single (individual) or multiple user (clinical) settings
Installation of Program	Internet link	Internet link	Internet link
Communica-tion Method	Cellular phone	Cellular phone	Cellular phone
Connectivity	Bluetooth	Bluetooth	Bluetooth
Display	Cellular telephone and monitors connected to a central server	Cellular telephone and monitors connected to a central server	Cellular telephone and monitors connected to a central server
Glucose Meters	LifeScan OneTouch® Ultra® and Ultra® II Meters; As additional software protocols are obtained and devices are validated, capabilities will be broadened to include other meters	Wide range of supported meters are listed on website; As additional software protocols are obtained and devices are validated, capabilities will be broadened to include other meters	LifeScan OneTouch® Ultra® Meter
Report Types	• Logbook • Readings line chart • Average bar chart • Percentage pie chart • Percentage readings by time of day	• Logbook • Readings line chart • Average bar chart • Percentage pie chart • Percentage readings by time of day	Various
Types of Information That Can Be Manually Entered	• Insulin list • Medication list • Laboratory results	• Insulin list • Medication list • Exercise • Blood pressure data • Laboratory results	Various

I. Standard/Guidance Document Referenced (if applicable):
None referenced

J. Performance Characteristics:

1. Analytical Performance:
    a. *Accuracy:*
        Not applicable
    b. *Precision/Reproducibility:*
        Not applicable
    c. *Linearity:*
        Not applicable
    d. *Carryover:*
        Not applicable
    e. *Interfering Substances:*
        Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

    Data transmission was validated to be accurate from the glucose meter to the Polytel GMA and to the SymCare Database. The validation process included the following steps **1.)** The 510(k) cleared PolyMap Wireless Polytel Glucose Meter Accessory (GMA) was connected to a One Touch Ultra 2 Meter, Blood Glucose Readings were taken following the Ultra 2 Meter directions for use and comments were added to the readings using the Meter. **2.)** These readings and comments were sent to the PolyMap when the Blood Glucose Test Strip was removed from the meter (as defined by normal PolyMap operation). **3.)** The PolyMap then sends the data to transient storage on the mobile phone application. **4.)** The mobile phone application then sends the PolyMap data log to the SymCare data receiver. **5.)** These data are then imported into the SymCare Diabetes Management Program (DMP) **6.)** The meter was then connected to the One Touch Data Management Software (OT DMS) to retrieve the initial readings and verified accurate data. Data elements used for validation were glucose readings, comments, time and date.

    Additionally a human factor's study was performed as follows:

    Participants:

    A total of 14 participants included in the study were defined as those diagnosed with Type 1 or Type 2 Diabetes and who were between the ages of 18 and 64. Participants were undergoing treatment for their Diabetes with either insulin or an oral agent and were regularly performing self monitoring of blood glucose (SMBG), without assistance, at a minimum of 2-3 times per day using the LifeScan Ultra or Ultra2 meter.

Health Care Professional Participants:

Health Care Professionals(HCP's) who participated in the study can be defined as those involved in the care and management of patients with diabetes type 1 and type 2 who are on insulin or a type of oral agent for the treatment of type 2 diabetes. There were 4 Medical Doctors, 1 Registered Nurse, and 1 Registered Dietician.

Methods:

Participants who were already proficient in SMBG using the LifeScan Ultra or Ultra2 meter utilized the Symcare Diabetes Management Program for a 7-day period. Following use of the device for a period of 7 days the participants provided evaluation of the Symcare Diabetes Management Program via a Human Factors Task Assessment and a User Comprehension Questionnaire on Day 7(+ 3 day window). These were administered by a study doctor or coordinator and took place at In-Center Visits on Day 5 and Day 7 (+ 3 day window). Medical team members also utilized the Symcare Diabetes Management Program during the 7-day period. An evaluation of the system was provided through a Human Factors Task Assessment and User Questionnaires administered by a Study doctor or coordinator, which specifically focused on the medical team user experience. It was noted that some patient's data did not transfer rapidly to the Symcare Diabetes Management Program secure website. The Symcare Diabetes Management Program allows for the transfer of a maximum of 100 readings from the meter at one time.

Discussion and Overall Conclusions:

The Primary Endpoint was met for each questionnaire for health care professionals and participants, which assessed human factors tasks, labeling comprehension and ease of use.

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.