5.0 510(K) SUMMARY

Submitter's Name	SymCare Personalized Health Solutions, Inc.
Address	965 Chesterbrook Blvd. Wayne, PA 19087
Establishment Registration Number	3007710797
Date of Summary	08-December-2009
Telephone Number **Fax Number**	484.686.4650 610.455.2334
Contact Person	Rae Ann DeLay, Director Quality, Regulatory & Compliance
Name of the Device	InTouch™•diabetes Version 2.1
Common or Usual Name	Accessory to a glucose test system
Classification Name	• Glucose Test System, 21 CFR 862.1345, Class II Product Code: NBW • Calculator/Data Processing Module for Clinical Use, 21 CFR 862.2100, Class I, Product Code: JQP
Performance Standards	There are no performance standards promulgated for this device.
Indications for Use	InTouch™•diabetes 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. InTouch™•diabetes 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.
Identification of the Legally Marketed Device (Predicate Device)	• SymCare Diabetes Management Program(DMP) V2.03, K083263 • MCT Diabetes Version 2.0, K073699 • Think Positive (t+) Diabetes Management System, K061328

510(k) SUMMARY, continued

Device Description

- InTouch™•diabetes 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.

- InTouch™•diabetes enables a blood glucose meter to connect via a Bluetooth accessory, the Polymap Wireless Polytel® GMA Glucose Meter Accessory (GMA), to a cellular phone in order to transmit meter readings to the InTouch™•diabetes online system, which is accessible by the healthcare provider as well as the patient. The Polymap Wireless Polytel® GMA(s) that are utilized by InTouch™•diabetes are currently marketed accessories cleared for OTC use via 510(k) K091296.

- Patients are offered insights into their condition and in partnership with their HCPs can engage in new self-management activities, including monitoring regimens. Education content and interactive communications with their caregivers, disease managers, or educators, are available.

- The InTouch™•diabetes application software that resides on the mobile phone transmits the patient's blood glucose measurement data from a glucose meter to the InTouch™•diabetes central repository database. The data is analyzed to recognize health patterns, show trends, and this information is displayed visually along with personalized health information and education.

- InTouch™•diabetes does not provide alerts/alarms, specific treatment or insulin does recommendations; or any advertisements and it meets the applicable HIPAA privacy requirements.

Substantial Equivalence

InTouch™•diabetes is similar to MCT-Diabetes K073699 and Think Positive (t+) Diabetes Management System K061328 in that all include software which is intended to assist in the review, analysis and evaluation of blood glucose test results. These systems share similar product components (cellular phone, blood glucose meter, website) and product interfaces (bluetooth connectivity). Both MCT-Diabetes K073699 and Think Positive (t+) Diabetes Management System K061328 are indicated for Over the Counter Use. inTouch™•diabetes was cleared by the FDA under the previous name, SymCare Diabetes Management Program in K083263.

510(k) SUMMARY, continued

Description and Conclusion of Testing

Non-clinical Testing:
Extensive software verification and validation testing was conducted and demonstrated compliance to requirements and design specifications. This testing included unit, integration and system level testing as well as user acceptance and load testing.

Clinical Testing:
A human factors/usability study was performed to measure the usability of the InTouch™•diabetes and/or to identify critical areas that require modification to improve comprehensibility. Additionally, a readability assessment of the user manual and the website was performed using the Fry Scale. The readability for user manual is at the 9th grade level while the website is the between 7th and 8th grade levels. This labeling provides adequate directions for use for the intended user (people 18 years of age and older) to use InTouch™•diabetes safely and for the purposes for which it is intended.

Conclusion:
The successful non-clinical testing and clinical testing demonstrates the safety and effectiveness of the InTouch™•diabetes Version 2.1 when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

FEB 19 2010

Symcare Personalized Health Solutions, Inc
c/o Rae Ann Delay
Quality, Regulatory & HealthCare Compliance
965 Chesterbrook Blvd,
Wayne, PA 19087

Re: k093789
Trade/Device Name: Intouch Diabetes
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: December 8, 2009
Received: December 9, 2009

Dear: Ms. Delay:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k093789

Device Name: InTouch™•diabetes

Indications for Use:

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Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __x____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

of In Vitro Diagnostic Device
and Safety

K093789