

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

A. 510(k) Number:
k093789

B. Purpose for Submission:
Symcare is seeking OTC clearance for the InTouch (formerly Symcare) Diabetes Management Program cleared for prescription use under k083263 using the Polymap Wireless Polytel GMA glucose meter data transmission accessory originally cleared under k070559 for prescription use and more currently cleared for OTC use under k091296.

The Symcare Diabetes Management Program has been renamed InTouch Diabetes Management Program.

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

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

- E. System Descriptions:**
1. Device Description:
The InTouch 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)” (k091296), 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:
External quality control is not applicable for data transmission.

8. Software:

FDA has reviewed the applicant's Hazard Analysis and software
Documentation: Yes X or No

Subject of k083263 review

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 2, I respectively

3. Product Code:
NBW, JQP

4. Panel:
Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

InTouch 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. InTouch 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):
None

H. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:

MCT Diabetes™ V2.0 k073699

2. Comparison with Predicate Device:

	InTouch™•diabetes Version 2.1	Original SymCare DMP 2.03 K083263	MCT Diabetes™ V2.0 K073699
Intended Users	Home users, healthcare providers (including SymCare healthcare professionals), and insurance payers	Home users by prescription, healthcare providers (including SymCare healthcare professionals), and insurance payers	Home use or clinical assist diabetics, families, and professionals in management of blood glucose support diabetes management
Prescription or OTC Use	OTC & Prescription	Prescription	OTC
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
Communication 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
Type of devices that can be interfaced	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	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

I. Standard/Guidance Document Referenced (if applicable):

None were 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:

Human Factors studies for the entire system with U.S. labeling, using lay people were performed to support the OTC claim.

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.