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

A. 510(k) Number:
k111509

B. Purpose for Submission:
New submission for an accessory data management software application for cleared glucose meters

C. Manufacturer and Instrument Name:
SweetSpot Diabetes Care, Inc.
SweetSpot Diabetes Data Management Service

D. Type of Test or Tests performed:
Diabetes data management system

E. System Descriptions:

1. Device Description:
   The SweetSpot Service allows patients or healthcare professionals to download data from blood glucose meters (BGM) and generates a report from the downloaded data, which is delivered to the healthcare professional for use in patient management. The Service is comprised of three different types of data retrieval stations, a Fetch Utility, a data processing and storage platform, report generation software, and an information delivery service.

2. Principles of Operation:
   The Service is Microsoft Windows and Apple OSX compatible, and is delivered as Software as a Service (SaaS) over the internet. The Service centrally manages data and activities through multiple, loosely-coupled units of functionality.

   The SweetSpot Service is comprised of 3 subsystems: Kiosk, Fetch Utility, and SweetSpot Platform. The Fetch Utility resides on a Kiosk and is updated from the Platform as needed. If the Back-Office Web Application is used, the Fetch Utility is called from the Platform for each instance of use (it does not reside on a standalone computer). The Platform resides on web.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?
   Yes X or No___.

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?
Yes ___ or No X__ .

If a BGM uses wireless or Bluetooth® communication, the Kiosk is capable of detecting these signals and downloading the BGM data using 802.11(g) or Bluetooth® 2.1 protocols.

The SweetSpot Service operates in the following manner:

- The patient or clinician "checks-in" (downloads) BGM data
- The BGM data are sent to the SweetSpot Platform on the Web
- The SweetSpot Platform performs various data processing steps on the BGM data
- The SweetSpot Platform generates a report from the BGM data
- The SweetSpot Service delivers the report to the clinician, and to the patient if requested

4. Specimen Identification:
   Meter controlled download to data manager
5. Specimen Sampling and Handling:
   Not Applicable
6. Calibration:
   Not Applicable
7. Quality Control:
   Not Applicable
8. Software:

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

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 and I respectively
3. Product Code:
   NBW - System, Test, Blood Glucose, Over the Counter
   JQP - Calculator/Data Processing Module, for Clinical Use
4. Panel:
   Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

The SweetSpot Diabetes Data Management Service is intended for use in clinical settings by both patients and healthcare professionals, to assist in the review, analysis, and evaluation of blood glucose test results by the clinician to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data interface capabilities.

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

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
   MyCareTeam-Diabetes (MCT-Diabetes) data management software k073699
2. Comparison with Predicate Device:

Similarities		
Item	**Device**	**Predicate**
Indication for use	Service is intended for use in clinical settings by both patients and healthcare professionals, to assist in the review, analysis, and evaluation of blood glucose test results by the clinician to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data interface capabilities.	same
User	patients and healthcare professionals	same
Data access	Accessed from a typical PC	same
Interface	Icon-based user interfaces	same
Meter	support commonly available blood glucose monitors	same
Reports	Automated reports to aid in diabetes management	same
Differences		
Item	**Device**	**Predicate**
Data Upload	Patient or Clinician at the clinic	Patient from home
Report	Reports are automatically sent to the clinician via a predefined workflow	reports to the clinician only after the patient has granted permission
Computer	Windows or Macintosh	Windows

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

- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- ISO15197:2003 - In vitro diagnostic test systems - Requirements for blood - glucose monitoring systems for self-testing in managing diabetes mellitus

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:

   A Human Factors study of 21 participants was performed to verify ease of use, label comprehension, meter data transfer in the hands of lay users. Additionally, meters are bench tested to verify data transfer compatibly and accuracy.

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**.**