DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax:(425) 302-0404 Industry Information: www.fda.gov/oc/industry	12/14/2015 - 12/18/2015
	FEI NUMBER 3009177686

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: George NMI Zamanakos, General Manager

FIRM NAME	STREET ADDRESS
SweetSpot Diabetes Care, Inc.	919 SW Taylor Street Suite 500
CITY, STATE, ZIP CODE, COUNTRY Portland, OR 97205	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically,

a. For three (3) of nineteen (19) Corrective and Preventive Action records (CAPAs) reviewed, I observed your firm did not document investigation into the cause of nonconformities according to your firm's procedure Corrective and Preventive Action, SOP-0500-5, as follows:

   i. CAPA-30 - Your firm identified that release of SweetSpot Diabetes Data Management System, r149, resulted in certain customers not being able to use the system, including breaking the ability to render PDF reports. Your firm did not document the investigation into the broken ability to render PDF reports, including documenting the identified root cause. Your firm closed this CAPA on 09/02/2014, and signed this CAPA as reviewed and approved on 12/14/2015.

   ii. CAPA-61- Your firm identified design documentation issues, including real-time stamps not being available, test dates did not always match pre-populated dates, and signatures appeared to be missing based on how files are being scanned. Your firm did not document the investigation into these documentation issues. Your firm signed this CAPA as reviewed and approved on 12/13/2015.

   iii. CAPA-72 - Your firm identified 318 inquiries related to download and installation issues with the Portrait on the Web device. Your firm identified the majority of notes indicated the user needed help downloading the installer file; your firm did not document investigation into the remaining inquiries, and listed the root cause as "N/A". Your firm closed this CAPA on 10/27/2015, and signed this CAPA as reviewed and approved on 12/13/2015.

b. For three (3) of nineteen (19) CAPAs reviewed, I observed your firm did not document verification and/or validation of the corrective actions to ensure such actions are effective and do not negatively affect the finished device according to

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	James D. Hildreth, Investigator	12/18/2015

your firm's procedure Corrective and Preventive Action, SOP-0500-5, as follows:

i. CAPA-30 - Your firm identified corrective actions including release of SweetSpot Diabetes Data Management System, r152, backwards compatibility testing for future releases, and creation of a test plan for automated and manual tests. Your firm did not document verification by examination and provision of objective evidence these corrective actions were effective. Your firm closed this CAPA on 09/02/2014 and signed this CAPA as reviewed and approved on 12/14/2015.

ii. CAPA-61 - Your firm identified design control documentation issues, including real-time stamps not being available, test dates not always matching pre-populated dates, and signatures appearing to be missing based on how files are being scanned. Your firm identified transferring responsibility for hazard analysis (b) (4), combining hazard documentation, and documenting contractor training as corrective actions, and specified "Check that subsequent products in development ((b) (4)) are consistent with these changes". Your firm did not document verification by examination and provision of objective evidence that these corrective actions were effective. Your firm signed this CAPA as reviewed and approved on 12/14/2015.

iii. CAPA 62 - Your firm identified corrective actions including " (b) (4) Software Release was updated to allow for faster response to minor and maintenance updates". Your firm specified " (b) (4) during the (b)(4) day VoE will be considered a failed VoE"; your firm did not document verification by examination and provision of objective evidence according to this requirement. Your firm closed this CAPA on 09/11/2015, and signed this CAPA as reviewed and approved on 12/13/2015.

OBSERVATION 2

Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary.

Specifically,

For two (2) of sixteen (16) complaints reviewed, I observed your firm did not document investigation into possible failures of your firm's devices according to your firm's procedure Customer Complaints and Communications, SOP-0501-5, as follows:

a. Complaint 379 was created on 07/29/2015 to address a report of a SweetSpot Diabetes Data Management System customer receiving blank and erroneous data on reports generated by your firm's device. The customer identified as part of this complaint an upload which contained 469 readings containing mostly out of normal range values, dated prior to the patient getting the device. Your firm did not document investigation into the possible report of erroneous data; your firm reported the root cause as "Not able to reproduce". On 10/05/2015, your firm closed the complaint ticket, and on 12/12/2015 signed the complaint as reviewed and approved.

b. Complaint 355 was created on 04/22/2015 to address a report that uploaded data in Portrait on the Web was dated in the future. Your firm identified that someone would be assigned to investigate the issue. Your firm did not document investigation into future-dated uploaded data; your firm reported that the issue could not be duplicated and the root cause

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cannot be determined. On 09/18/2015, your firm closed the complaint ticket, and on 12/12/2015 signed the complaint as reviewed and approved.

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Observation Annotations

Observation 1: Promised to correct.

Observation 2: Promised to correct.

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