Establishment Inspection Report	FEI:	3004753838
DexCom, Inc.	EI Start:	1/11/2010
San Diego, CA	EI End:	2/8/2010

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SUMMARY

This "for cause" inspection of a Class III device manufacturer of the Seven Continuous Glucose Monitoring System (CGMS) was conducted under FACTS assignment 113124 and was performed in accordance with LOS-DO's FY'10 work plan assignment. This inspection was performed in response to CDRH/OIVD information suggesting failure of the firm to report Medical Device Reporting events. The inspection was conducted in accordance with C.P.7382.845-Inspection of Medial Device Manufacturers (PAC Codes 82845G, 81011 and 82012) and covered Profile Codes PRF, ELE and MTL.

The previous inspection conducted from 11/5/08 to 12/10/08 was a Post-Market inspection that covered the change in the firm's manufacturing location. The inspection resulted in the issuance of a four (4)-item FDA-483. Deficiencies noted included not following procedures for controlling environmental conditions and incomplete documentation for design verification test protocols. Three of the four items were corrected prior to the close-out meeting. A complete response was sent to the attention of LOS-DO's District Director. The inspection was classified VAI.

The current inspection covered Management Controls, Production and Process Controls, CAPA, complaints and medical device reporting (MDR). The inspection revealed the firm's failure to report MDR events to FDA. Further, the firm's representatives are not following their

complaint/MDR and CAPA procedures. A seven (7)-item FDA-483 was issued to the firm's Vice President. He promised to correct the deficiencies and further, he promised to provide a written response within (b) (4) days to LOS-DO's District Director. A documentary sample (DOC 427960) of the firm's STS sensor wire was collected to document interstate commerce and off-label use.

ADMINISTRATIVE DATA

Inspected firm:	DexCom, Inc
Location:	6340 Sequence Drive San Diego, CA 92121
Phone:	858-200-0200
FAX:	(858)200-0201
Dates of inspection:	1/11/10, 1/12/10, 1/13/10, 1/14/10, 1/21/10, 122/10, 2/01/10, 2/03/10 and 2/08/10
Days in the facility:	9
Participants:	Trudy R. Papson, Investigator

On 01/11/2010, I presented my credentials and issued an FDA-482 to Andrew K. Balo, V.P. of Clinical and Regulatory. Mr. Balo said he is the most responsible person at the firm, in the absence of Terrance (aka Terry) H. Gregg, President and CEO. Mr. Gregg was not present during the entire inspection. Due to time away from the firm, a second FDA-482 was issued to Mr. Balo on 2/1/10.

Mr. Balo said there are approximately (b) (4) employees located at the firm. He said the firm's hours of operation are listed as follows:

(b) (4)

The firm's medical device registration for establishment type manufacturer and listing is current for 2010.

All official correspondence should be addressed to:

Terrence H. Gregg, President and CEO

6340 Sequence Drive
San Diego, CA 92121

HISTORY

Mr. Balo said the firm's history of business has not changed since the previous inspection. He said the firm was incorporated within the State of Delaware, in May 1999. I collected a listing of

the Board of Directors with short biography of each person, **Exhibit 14.** Mr. Davalos also provided me with the DexCom 2008 Annual Report, **Exhibit 15.**

INTERSTATE COMMERCE

Mr. Balo said approximately (b) (4)% of the firm's medical devices are shipped in interstate commerce to customers located throughout the United States. The firm also distributes devices worldwide.

Mr. Balo said the firm's devices are promoted via brochures, trade shows, international sales force and via the firm's website www.DexCom.com.

Mr. Balo said the firm utilizes (b) (4) as their primary carrier for distribution of products worldwide.

JURISDICTION

The firm's Continuous Glucose Monitoring System (b) (4) is a Class III medical device. Originally, the device was sold directly to physicians and independent clinics under the trademark name of DexCom STS Continuous Glucose Monitoring System. Mr. Balo said Glucose Monitors are also shipped directly to patients and distributors.

Mr. Davalos, Director of Quality Assurance provided me with copies of product labeling for the Seven Plus Continuous Glucose Monitoring System as follows.

Exhibit 1: Instructions for Use, DexCom STS Continuous Glucose Monitoring System
Exhibit 2: User's Guide, DexCom STS Continuous Glucose Monitoring System
Exhibit 3: Quick Start Guide DexCom Continuous Glucose Monitoring System
Exhibit 4: Limited Warranty Card
Exhibit 5: Training Worksheet DexCom CGM
Exhibit 6: Tips for Using Seven Plus CGM DexCom
Exhibit 7: Your Patient's G.P.S (Glucose Protection System) Brochure
Exhibit 8: Your Personal G.P.S. (Glucose Protection System) Brochure
Exhibit 9: DexCom 2009 Continuous Glucose Monitoring (CGM) Coding Reference
Exhibit 10: Is Continuous Glucose Monitoring Right For You Brochure
Exhibit 11: CD of DexCom Seven Sensor Kit Labels
Exhibit 12: CD of DexCom Seven Plus Starter Kit labels
Exhibit 13: CD of DexCom Website www.dexcom.com

I requested and Mr. Davalos provided me with a copy of the firm's distributor listing. This list contains names and addresses, **Exhibit 16.** I also requested and received the firm's complete

product listing. This list contains part numbers and indicates whether the device is sold in the U.S., **Exhibit 17.** Mr. Davalos provided me with a copy of the firm's current product and replacement listing. This list indicates the sensor 4-pack part numbers and various kit numbers, **Exhibit 18.**

Mr. Davalos also provided me with a listing of the total quantity of sensor wires shipped in 2009 and the total quantity of the STS system and sensors in the firm's inventory as of 2/1/10, **Exhibit 19.**

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Balo said Terrance H. Gregg, President and CEO is ultimately the most responsible person at the firm. Mr. Balo identified himself as a member of management with executive responsibility. Mr. Balo provided me with a copy of the firm's organizational chart, **Exhibit 20.**

Andrew K. Balo, Senior V.P., Clinical and Regulatory: Mr. Balo said he reports directly to Terry Gregg, the firm's President and CEO. Mr. Balo was present on and off throughout entire inspection. Mr. Balo said his day-to-day responsibilities include compiling and submitting PMA Supplements associated with P050012, and overseeing any associated manufacturing changes. He said he writes and develops verification and validation protocols. Mr. Balo said he also monitors clinical studies and compiles data for clinical reports. Mr. Balo said he has the authority to hire and fire personnel. He said he does not have the unilateral authority to implement a product recall. His authority regarding a FDA-483 corrective action is to be part of the review team that determines the appropriate corrective action response.

Paul (NMI) Mason, PhD., Senior Director, Regulatory Affairs: Mr. Mason said he has been with the firm since April, 2009. He said his day-to-day responsibilities include directing, managing and organizing the firm's regulatory affairs activities, filing adverse event reports (MDR), managing the internal audit functions, preparing U.S. and O.U.S. regulatory medical device submissions, and reviewing labeling and marketing information. Mr. Mason said he has the authority to hire and fire personnel. However, he does not have the authority to unilaterally implement a product recall or a FDA-483 corrective action. With regards to a FDA-483 corrective action, he is part of the review team that determines the appropriate corrective action response.

Mr. Mason was present throughout the inspection. He answered questions and provided information and records related to sensor wire fractures and sensor failure investigations and CAPA activities. Mr. Mason also provided information relating to the next generation (b) (4) (b) (4) PMA supplement to FDA. He said the new (b) (4) (b) (4) . Mr. Mason provided information relative to the firm's PMA supplements / submissions and pending activities. He said he reports to Mr. Balo.

Trent E. Davalos, Director of Quality Assurance: Mr. Davalos was present throughout the inspection. Mr. Davalos said he has worked for the firm since June, 2008. Mr. Davalos provided answers and documents pertaining to the firm's quality system. Mr. Davalos said his day-to-day

responsibilities at DexCom include reviewing device history records, conducting QSR training, maintaining the firm's document control system, approving device master records, maintaining nonconforming product documentations and overseeing complaint evaluations. He said he has the authority to hire and fire personnel and to implement FDA-483 corrective actions within his area of responsibility. He said he does not have the authority to unilaterally implement a product recall. Mr. Davalos provided procedures and records such complaints, MDRs and device history records. Mr. Davalos said he reports to Mr. Balo.

Bradley S. Matsubara, MD, Director of Clinical Affairs: Dr. Matsubara said he is the in-house medical officer designated to contact patients when a call is escalated due to complaints such as broken sensor wires and infections. Dr. Matsubara answered questions related to emails he sent associated with complaints and his involvement with complaint handling. Dr. Matsubara said he reports to Mr. Gregg.

Sarah V. Bruno, Supervisor, Technical Support: Ms. Bruno said she has worked for the firm since 10/2006. She said she was hired as a Technical Support Representative. She said she worked in this position until she was promoted to the position Technical Support Supervisor in 1/2009. She said she works with customers and handles complaints via the telephone and is responsible for documenting data in the firm's complaint database. She said she supervises the firm's (b) (4) Technical Support Representatives. She said she takes calls that have escalated due to patient concerns. She said she provides high-level technical support and resolves escalated patient concerns. Ms. Bruno said she developed the Technical Support Troubleshooting guide. Prior to working at this firm, she said she worked as a Q.A. Specialist (b) (4) . She said she also worked as a Research Associate at (b) (4) . Ms. Bruno said she does not have a medical background, license, or medical training. Ms. Bruno also assisted as transcriber during the inspection. She said she reports to Mr. Balo.

Additional persons interviewed during the current inspection are listed as follows:

Kate C. Hunter, JD, Regulatory Affairs Associate provided assistance in obtaining and keeping track of document requests and acted as transcriber.

Jeff Moy, Vice President of Operations provided information and regarding sensor testing.

Jeffrey Jackson, PhD, Director, Manufacturing provided information during the walk-through of the manufacturing and sensor calibration check station.

MANAGEMENT CONTROLS

I reviewed the firm's Quality Manual and Quality Policy, QM, 000000, Rev 3. Management reviews are conducted in accordance with the firm's Quality Manual. I reviewed the agenda items from the last Management Review Meetings held in (b) (4) and (b) (4). The cover sheet includes the meeting agenda and the attendees. Management with executive responsibility was in attendance and no observations were noted.

PURCHASING CONTROLS

I reviewed the firm's Supplier Program procedure, SOP, 3000019, Rev 3. I reviewed the Supplier Survey Checklist, (b) (4) and supplier qualification for the (b) (4)% Glutaraldehyde received from (b) (4). The firm has a signed agreement. No observations were noted.

DESIGN OPERATIONS

The glucose monitoring system includes three major units: (b) (4)

(b) (4)

This is a prescription device and is intended for home use and in health care facilities as an adjunctive device to complement, but not replace, blood glucose information obtained from a standard home glucose monitoring device. This PMA device is intended for use in adults over the age of 18 and for (b) (4).

The sterile sensor is inserted, via a syringe applicator, into (b) (4) for continuous monitoring (b) (4). The transmitter is attached to the sensor pod which adheres to the abdomen to provide readings to a remote small external receiver.

The firm's design controls were covered during the previous inspection. (b) (4) (b) (4) (b) (4) (b) (4).

PRODUCTION AND PROCESS CONTROLS

Mr. Davalos provided me with a copy of the firm's floor plan, **Exhibit 21.**

(b) (4)

I reviewed the Seven STS-7 Device Master Record and Master Validation Plan. I reviewed the Post CAL-Check Analysis-(b) (4), Rev: 03, 6/09 and Sensor In-Line CAL Check-(b) (4) procedures. I reviewed a completed Cal Check ID and Sensor Serial Number form (b) (4) No observations were noted in the final Cal Check and in-line testing records.

I also reviewed 11 device history records (DHR) in accordance with binomial sample Table 1, Row A. The eleven (11) DHR's were selected at random. Mr. Davalos said the firm calls the DHR a Lot History Record (LHR) for each device.

The LHR's include production records for the sensor (b) (4) and the sensor applicator (b) (4). The laser skiving, electrode, enzyme and resistance layer coating are also identified and included with the line clearance and Cal Check and Post Check Analysis. The DHRs appeared adequate and no observations were noted.

I reviewed the firm's non-conformance reports for 2009 and observed the firm is not re-working non-conforming sensor wires. Mr. Davalos said the firm scraps all rejected sensor wires. I reviewed copies of the firm's scrap destruction and pick-up report and found scrapped wires had been picked-up for recycling.

MANUFACTURING CODES

The firm uses a lot numbering system as their method of traceability for components used in the build of the DexCom STS Continuous Glucose Monitoring Systems. An example of this lot numbering system is: (b) (4)

(b) (4)

COMPLAINTS/MDRS

I reviewed the firm's complaint procedure, SOP-140200, Revs 8-13, **Exhibit 22.** I requested the revisions dating back to 2008. I also requested and received a copy of the firm's (b) (4) database showing all sensor and sensor wire fracture complaints. I requested the CD to include all fields and all complaints received by the firm for sensor wire breakage or possible fractures from 2008 to present. Mr. Davalos provided the CD, **Exhibit 23**. The database is extremely difficult to follow as the firm places each conservation with a patient into a separate column or line item and multiple reports are included under one complaint number as exampled by:

CD showing CR 08-(b) (4): Dr. Matsubara's email reads in part:"***Talked with (b) (6) (patient). He said 6 out of 12 sensor wires were left in his skin*** (b) (4) "***10/24/08***".

CD showing CR 09-(b) (4): Dr. Matsubara email and complaint reads in part:"*** (b) (6) says he can feel the wire under his skin and he thinks the entire part of the wire that senses beneath the skin is still beneath his skin. He said he has also removed 2 sensors previously where the wire broke beneath the skin. Patient did not give me the L/N before I transferred him***5/18/09***".

CD showing CR 08-(b) (4): Email between Dr. Matsubara and (b) (6) reads in part:"***So sorry to bother you again. I've had lots of reports of broken sensor wires lately. I assume you would like us to report all of them. 2 wires reported broken in skin. (b) (6) (patient) had another wire break off after removal***8/19/08***".

CD showing CR 08-(b) (4): Reads in part:"***Removed sensor to only find out the wire is stuck in his abdomen***". Dr. B. Matsubara to (b) (6), "This sounds like the wire was just left behind, but it sounds like he is expecting a call back***8/20/08***".

I noted the CD contains over (b) (4) line items. However, Mr. Mason said the firm has only received (b) (4) broken wire complaints. I asked how the firm is able to capture the actual number of sensor wire complaints given their database just contains line items of various discussions. Mr. Davalos said he wasn't sure. I randomly selected 34 of the (b) (4) complaints on the firm's database for review in accordance with binominal Table 2, Row B.

I noted much of the patient information has been left blank on the hard copy received. Ms. Bruno said this is because these are copies and the information is captured in the database. However, I observed this information was also missing from the database, such as the patient's birth date and emails mentioned from Dr. Matsubara. Ms. Bruno said those are kept on-file and scanned into the database. I requested examples of Dr. Matsubara emails referenced. Dr. Matsubara said he keeps the emails on his computer, **Exhibit 24**. I noted some of the emails could not be located on the CD such as the one dated 12/28/09 from (b) (6), **Exhibit 24, page 17.** In addition, multiple sensor wire breakage is discussed but not shown on the CD, **Exhibit 24, page 3.** I also observed Dr. Matsubara is advising patients to not retrieve the wire unless signs/symptoms occur, (e.g. email dated June 3, 2008) **(Exhibit 24, Page 23)** and the doctor is aware of the usage in pediatric patients (off-label), (e.g. email dated March 31, 2008), **Exhibit 24, (see pages 13 and 20).**

I continued to request confirmation of the total actual number of broken sensor wire complaints which as of 2/8/10 still could not be provided. Mr. Mason said the firm's best guest is about (b) (4). He provided me with Medical Device Reports for all (b) (4) wire fracture complaints. Mr. Balo said he decided to report these (b) (4) cases as adverse events. I collected MDRs and the associated complaints, **Exhibit 25.** The attached list shows the complaints involving pediatric patients.

My review of the complaint records revealed no MDR reports are on file. Mr. Mason stated he did not agree with the Agency regarding submission of MDR's for fractured sensor wires under patient's skin as there were no deaths or serious injuries causing permanent injury to a patient. On 1/14/10, Mr. Balo provided me with a memo stating the firm will file MDR reports regarding broken sensor wires and other adverse events, **Exhibit 26.** Mr. Balo said the variance for reporting all events on one MDR was denied by CDRH.

I reviewed MDRs submitted to FDA. I noted the FDA Form 3500A did not contain in Block A the patient's age or date of birth. Mr. Davolos said the firm receives prescriptions for patients and other medical information so that they can supply the devices. He said the firm is able to locate this information, if required. I also stated this information could be obtained during the phone call with the patient. He agreed that this information is reasonably known to the firm.

I observed 7 out of 27 MDR reports reviewed and provided to FDA did not include the age of the patient, as exampled by reports 3004753838-2010-00001, 0006, 00011, 00013, 00023, 00025 and 00027, **Observation 4, (see Exhibit 25, MDRs are listed in chronological order).**

I also noted the FDA Form 3500A did not accurately contain in Block B the date of report by the initial reporter, **Observation 5, (see Exhibit 25, MDRs are listed in chronological order).** Specifically, (b) (4) FDA-Form 3500A reports submitted to FDA during this inspection did not include the actual date of filing the report to FDA, as exampled by the following:

1. MW 3004753838-2010-00001: Date of event was 1/5/09. The date of this report is 1/5/09.
2. MW 3004753838-2010-00010: Date of event was 4/21/09. The date of this report is 4/22/09.
3. MW 3004753838-2010-00073: Date of event was 12/29/09. The date of this report is 12/29/09.

The actual filing date is 1/29/10. On 2/8/10 Mr. Mason provided a copy of the (b) (4) tracking document and stated this was for the (b) (4) MDR's he sent to Mr. Huff at CDRH. The date on the document is 1/29/10. **(see Exhibit 39 and observation discussion #4).**

I also noted the firm's complaint handling procedures have not been implemented to ensure that all complaints are processed in a uniform and timely manner. Specifically, the firm is not closing complaints in a timely manner as exampled by complaint 08-(b) (4). The complaint was opened on 9/30/08 for sensor wire breakage. The complaint was closed during this inspection on 1/22/2010, **Observation 6, Exhibit 27.**

Mr. Mason said the firm has conducted some investigations into complaints of broken sensor wires but the majority is being studied (b) (4) **(see Exhibit 34).** He said if the wire is not returned no investigation is conducted, **(see Exhibit 40).** However, during my review of records I observed some investigations have been conducted when the wire has been returned and are recorded as memos to the file, (e.g. complaint 09-(b) (4) and 09-(b) (4) **see Exhibit 40).**

I asked Mr. Balo if the firm had ever submitted an adverse reaction and device defect report to FDA, as stated in their complaint handling procedure. He said no. I asked Mr. Davalos how the firm was able to track each sensor wire fracture complaint when multiple wires are complained about. He said the firm only captures the information by person or complainant and not based on the number of wires. He said he could not pinpoint this information for me.

I stated the firm has not implemented their complaint handling procedures. For instance, the firm's complaint procedure, SOP-140200 requires the firm to submit an Adverse Reaction and Device Defect Report to FDA within (b) (4) days of knowledge of any adverse reaction or injury to a patient. This report has not been submitted to FDA within (b) (4) days of an adverse reaction or injury, **Observation 3, #1, Exhibit 22, (see page 4 and 20).**

In addition, the firm's complaint procedure, SOP-140200 requires the firm to initiate a customer complaint after receipt of a potential complaint. The firm is documenting multiple complaints of sensor wire breakage under one complaint number, as exampled by 03-(b) (4), **Observation 3, #2,**

Exhibit 27, (see page 32).

I also reviewed the firm's Medical Device Reporting procedure, SOP-300024, Rev 01, **Exhibit 30.** The Adverse Reaction and Defect Report is also required as part of that procedure. Mr. Mason said no MDR reports have been submitted to FDA. However, during the inspection, MDRs were submitted (b) (4) to FDA on 1/29/10.

I stated the firm has not submitted an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. I provided as examples the following complaints related to sensor wire fractures under patient's skin, **Observation 1, Exhibit 25.**

1. Customer Report: 09-(b) (4), dated 7/11/2009 reported a sensor wire broke off in a three (3) year old and reported a piece of it was under her skin. The mother reported the child had surgery under general anesthesia to remove the broken wire underneath her skin, **(Exhibit 25, pages 188-194).**

2. Customer Report: 09-(b) (4), dated 1/6/09 reported the sensor wire tip broken off in patient's body. The DexCom representative advised patient's not to pursue extraction. The report states "sensor break with fragment retained under the skin", **(Exhibit 25, pages 2-11).**

3. Customer Report: 09-(b) (4), dated 5/07/09 the report states the nurse went to pull the old sensor off and the sensor wire was not there. The patient's nurse reported she could see it under the skin but she could not get hold of it with tweezers and then it disappeared. The nurse thinks "it came off and is still in his skin", **(Exhibit 25, pages 89-95).**

4. Customer Report: 09-(b) (4), dated 5/18/09. Patient reports 2 sensors have broken off under his skin. His most recent sensor looks broken upon removal today, and he can feel the wire under his skin. Site is red and he is going to prescribing physician, **(Exhibit 25, pages 98-104).**

5. Customer Report: 09-(b) (4), dated 7/20/2009. Patient called to report a failed sensor and said he has irritated skin. Patient reported he thought the wire came out completely, but his doctor removed a "hair like structure" from under his skin, **(Exhibit 25, pages 227-233).**

6. Customer Report: 09-(b) (4), dated 6/172009. Patient is a 30 month old child. Mother called to report sensor wire breakage under skin of child. The patient was taken to the ER when an infection developed, **(Exhibit 25, pages 127-135).**

During my review of the firm's complaints, it appears the wire fracture is preceded by an early sensor shutoff signal from the device. I observed the following:.

- Early Sensor Shutoff (ESS) after calibration
- No initial calibration
- Inaccurate blood glucose values
- ESS prior to double blood drop prompt
- ESS prior to double blood drop prompt (no wire)

- Moisture spike
- Painful insertion or blood at site
- ESS due to sensor noise
- Poor patch adhesion
- FS UL do not correct STS readings
- No wire at sensor removal
- Broken sensor wires

When reviewing hard copy complaints and the CD, I was able to identify "Broken Sensor Wire" complaints by searching for (b) (4), the assigned number for broken sensors. The patients report that upon removal of the wire they notice it to be shorter than usual and feeling something under the skin and complaints stating the user was unable to remove the wire with tweezers as it "disappeared". Users reported they had more than one broken wire imbedded in their skin, **(See Exhibit 25, pages 89-95).**

On 1/11/10, I asked Mr. Balo if any MDR's had been reported by the firm for complaints CDRH/OIVD discussed with him and Mr. Mason on 8/31/09. Mr. Balo stated the firm has not reported any MDR event since release of the PMA, the Seven Continuous Glucose Monitoring System, in 4/06.

My review of the FDA database revealed MedWatch reports on file submitted by user facilities but not by the firm. This issue was also discussed with the firm during a 9/09 conference call with CDRH/LOS. Mr. Balo stated it was difficult to identify the complainant without having the exact patient/complainant information. He said the firm could not provide an accurate accountability of an exact failure investigation.

On my initial walk-through, I toured the Customer Service and Technical Support Department. I observed Technical Support staff taking calls and discussing reports of sensor failures. The support staff was advising patients how to possibly correct the problems using a Trouble Shooting Guide, **Exhibit 28.** I later asked for an electronic copy of this guide. I received four sets on CD of the guide from Ms. Bruno, **(Exhibit 29).** I asked who developed the guide and Ms. Bruno said she did along with Dr. Matsubara's approval.

I asked Ms. Bruno if she could walk me through the Technical Support system. She demonstrated the templates where the data is filled in when talking with the complainant. She explained if there is a patient concern, an email is sent to Dr. Matsubara, the Quality Affairs Department, Mr. Mason and Mr. Balo.

I asked Ms. Bruno if she had ever taken a call where a user reported a broken sensor wire. She said yes. I asked to see the emails associated with each complaint I reviewed. She said the emails are embedded into the electronic complaint file. She said all data is scanned into their computer system and the electronic data is the official copy. I asked if she had a procedure book or other information the firm uses to discuss patient issues and concerns. She said the troubleshooting guide is used for this and she is able to look at it electronically as needed.

I asked Ms. Bruno, Technical Support Supervisor for information on training of the Technical Support staff and how they knew what codes to enter for patient injury, broken sensor wire and when to send a replacement. She said they had complaint training and had an on-line guide to read to the patients.

Mr. Davalos said he is in charge of maintaining the firm's complaint files. He said the firm's complaints are trended on a weekly basis by components which make up the STS Continuous Glucose Monitoring System (e.g., sensors, receivers and transmitters).

I noted during my review of complaint records that complaints were listed as "inconvenience" and many had a scripted statement typed in about the broken sensor wire. Ms. Bruno said she and the CES staff advised patients from a standard script she had written that according to doctor's the broken sensor wires were better off left alone, and advised patients not to attempt to have them removed (see below). I asked Ms. Bruno if she had any medical background, experience or training to which she said no.

Excerpt from DexCom Seven Plus Technical Support Troubleshooting Guide. LBL-010164-Rev 03, **(See Exhibit 28).**

Class Code: (b) (4)

Detailed Symptom: Broken Sensor Wire Sensor wire broken at or prior to removal, or sensor wire left in skin at removal. *Notify complaint coordinator immediately if this issue occurs.

(b) (4): Broken Sensor Wire : (b) (4)

(b) (4)

Please notify QA, In-house MD, and regulatory immediately via email and let the patient know that the in-house MD will be contacting them. Instruct the patient to leave the site alone.

Please state the following to the patient:

(b) (4)

Ms. Bruno said the above script is read to every patent reporting a broken sensor wire imbedded in their skin.

The CGMS device is intended for adults over the age of 18 and the site of sensor insertion is shown as in the abdomen only. I noted many complaints were for pediatric patients and for adults using the device in areas other than the abdomen.

Ms. Bruno stated that physicians order the CGMS devices for the pediatric patients. Ms. Bruno stated some adult patients prefer to use the wire in other areas, such as the arm, buttocks and thigh because they get a better reading and less noise. He said this use is considered an off-label use. Ms. Bruno stated their Technical Support Staff and Dr. Matsubara inform patients and guardians of minors and physicians that if the device is used in other areas of the body, that this is considered an off-label use.

I asked Ms. Bruno if the firm sells sensor wires separately. She stated sensor 4-Pack's are sold to patients as they request. She stated a prescription would be on file for the patient. She added the firm replaces individual sensors free of charge when a complaint is received of a broken sensor wire or other sensor failure, even if the usage was off-label.

Mr. Balo also said it is a company policy to replace sensors free of charge. I asked if any patients had been charged for broken wires. Mr. Davalos researched the issue and found (b) (4) (b) (4)

I observed on the complaint CD and in complaints I reviewed noticed that the firm's Clinical Education Specialists have provided training and re-training to parents of pediatric patients on the insertion of the wire. I also noted statements on the complaints CD that the firm's staff have consulted adult patients in the insertion of the device in other than the abdomen area (off-label use) **(see Exhibit 23).**

CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

I reviewed the firm's CAPA procedure, SOP-140000, Rev 07, **Exhibit 31.** I also reviewed the firm's non-conformance reports (NCProduct) and corrective action requests (CAR) from 2008 to present. I reviewed the firm's CAPA log from 2008 to present and requested to see the CAPA associated with fractured sensor wires (C-8012-J), **Exhibit 32.**

I noted the firm did not include corrective and preventive actions to correct or prevent recurrence of sensor wire fractures, **Observation 2, #1.** The firm opened CAPA, C-8012-J, dated 7/24/08 to investigate sensor wire fractures. The CAPA was closed 7/23/09. The firm continues to receive complaints of sensor wire fractures in patients in 2010. The CAPA (C-8012-J) did not include actions needed to correct or prevent recurrence of sensor wire fractures. Mr. Mason said the firm is addressing this issue under a pending PMA (b) (4) supplement.

I also observed the firm did not follow their CAPA procedure, SOP-140000 which requires corrective and preventative actions to prevent the recurrence of a potential nonconformity or other undesirable situation (C-8012-J), **Observation 2, #2.**

Mr. Balo said the firm recently opened CAPA C-9005-G to study the "railing" and ESS failures,

Exhibit 33. This CAPA documents the firm's management decision to change the wire to It was through this CAPA that the firm established a new wire made of (b) (4) which may be less prone to metal fatigue. This firm's studies have wire breakage is due to the wire breaks due to fatigue or weakening in the metal of the existing wire as it bends and flexes in the body. Mr. Balo said the firm is planning a design change to use a stronger wire to prevent this from happening. He said the studies and new design information has already been submitted to FDA for review. Documents were collected as part of CAPA C-9005-G and are enclosed with **Exhibit 33.**

Mr. Mason said no new CAPA had been opened after C-8012-J to address sensor wire fractures. As part of CAPA C-9005-G, this issue was studied and the results are provided in an investigation report entitled " Root Cause Investigation: Sensor Fractures, (b) (4) , **Exhibit 34.**

TRAINING

I reviewed a copy of the firm's training procedure, SOP-180100, Rev 07. I requested to review training records for the executive management, the Clinical Education and Technical Support staff. The records show Dr. Bradley Matsubara, Paul Mason, Sarah Bruno and (b) (6) Technical Support are trained in the firm's Quality System and in Adverse Event Reporting.

I requested the Clinical Education Specialist's (CES) job description. Mr. Davalos provided this record for review. The job description shows the CES employees work in the field training physicians and patients on the use of the Glucose device, **Exhibit 35.** They also receive complaints directly from physicians and patients. I requested a list of all CES employees with the CES location and contact information. (b) (4) , **Exhibit 36.**

The complaints I reviewed revealed employees are advising patients not to seek medical attention or to ignore malfunctions of the system, such as broken wires under the skin. Other symptoms are also being disregarded such as redness, bumps under the skin, possible infections and skin irritation. I made an observation that Dr. Matsubara, Director of Clinical Research and in-house medical officer and Sarah Bruno, Technical Support Supervisor specifically failed to follow the firm's MDR reporting procedure, SOP-300024 after talking with patients involving sensor wire breakage under the skin, redness, irritation and other conditions, as exampled by complaint 09-(b) (4), **Exhibit 25, pages 55-60.** The firm's MDR procedure requires the firm to prepare a Device Defect Report for any adverse reaction, side effect or sensitivity that is attributed to the device. No such report has been prepared or sent to FDA as per the firm's procedure, **Observation 7.**

RECALL PROCEDURES

I reviewed the firm's Corrections and Removals Procedure, Rev 02, **Exhibit 37**. Mr. Balo said the procedure identifies that upon receipt of a potential recall situation, the V.P. of Regulatory Affairs is to be notified. In the absence of the V.P., RA, the Director of QA is notified. After which, a recall team is assembled to develop a recall plan to ensure that such activities as establishing.

Mr. Balo said the process for a recall is that a chronology of events is developed where the firm determines the impacted catalog/serial numbers and quantities of product. The firm then identifies the consignees and conducts a health hazard analysis to determine the classification of the recall. He said they will also identify the CAPA activity necessary to first correct the recall issue then to prevent the reoccurrence of the event and determining a timetable for completion. Mr. Balo said he will propose advisory notices and determine whether a public warning is needed. He said he will notify FDA, if necessary and monitor the effectiveness.

Mr. Balo said the firm does not plan to issue a product recall for the wire fracture issue but it is being studied. I made an observation through my review of complaint records that the firm is replacing wires that have fractured and have developed a design change in response to sensor wire fractures. Mr. Balo said he is considering a correction and removal as a possible action but none has been planned thus far. Mr. Balo provided a memo dated 1/14/10 confirming that no field corrections have been initiated, **Exhibit 38.** Mr. Balo said the firm replaces devices when a customer complains as it is company policy and customer good will.

REFUSALS

No refusals were encountered.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

On 2/8/10, I issued a 7-item Inspectional Observation, FDA-483, to Andrew K. Balo, Senior Vice President of Clinical and Regulatory Affairs, the most responsible person at the firm. Also in attendance at the close-out meeting were the firm's following management personnel:

Trent E. Davalos, Director of Quality Assurance
Paul Mason, PhD, Senior Director of Regulatory Affairs.
Sarah V. Bruno, Supervisor Technical Support
Kate C. Hunter, JD, Regulatory Affairs Associate

Prior to the issuance of the FDA-483, I presented an Affidavit to Mr. Davalos, Director of Quality Assurance. Mr. Davalos said he could not sign the affidavit because it was against company policy. I asked him if he could review the affidavit and verify the records collected were accurate and complete. Mr. Davalos read the affidavit, looked at the documents and stated he could not comment, per company policy.

Prior to the FDA-483 discussion, I explained the FDA-483 represented my observations of objectionable conditions made during the inspection and that these conditions might be determined, after review by the Agency, to be violations of the Federal Food, Drug and Cosmetic Act which could result in the issuance of a warning letter or other regulatory actions. I also

explained the agency's new policy, regarding responses need to be made to the district within a 15 business day timeframe.

I read each observation out loud to the firm's management. I discussed the Inspectional Observations with Mr. Balo and provided him with an opportunity to respond. Mr. Balo annotated each observation with promise to correct within a certain timeframe. Mr. Balo said he would send a written response to the Los Angeles District Director within 15 days.

Observations listed on form FDA 483

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the firm failed to submit MDR reports to the FDA for complaints involving sensor wire fractures underneath patient's skin as exampled by:

1. Customer Report: 09-(b) (4), dated 7/11/2009 reported a sensor wire broke off in a three (3) year old and reported a piece of it was under her skin. The mother reported the child had surgery under general anesthesia to remove the broken wire underneath her skin.

2. Customer Report: 09-(b) (4), dated 1/6/09 reported the sensor wire tip broken off in patient's body. The DexCom representative advised patient to not to pursue extraction. The report states "sensor break with fragment retained under the skin".

3. Customer Report: 09-(b) (4), dated 5/07/09 the report states the nurse went to pull the old sensor off the sensor wire it was not there. The patient's nurse reported she could see it under the skin but she could not get hold of it with tweezers and then it disappeared. The nurse thinks "it came off and is still in his skin."

4. Customer Report: 09-(b) (4), dated 5/18/09. Patient reports 2 sensors have broken off under his skin. His most recent sensor looks broken upon removal today, and he can feel the wire under his skin. Site is red and he is going to prescribing physician.

5. Customer Report: 09-(b) (4), dated 7/20/2009. Patient called report a failed sensor and has irritated skin. Patient reported he thought the wire came out completely, but his doctor removed a "hair like structure" from under his skin.

6. Customer Report: 09-(b) (4), dated 6/172009. Patient is a 30 month old child. Mother called to report sensor wire breakage under skin of child. Patient taken to the ER when an infection developed.

Annotation: Promise to Correct by 3/8/2010

Reference: 21 CFR 803.50(a) (2)

Relevance: MDR reports not filed with FDA.

Discussion with Management: Mr. Balo said he promise to correct and will provide a written response to FDA within 15 days.

OBSERVATION 2

Corrective and preventive action activities have not been documented, including analysis of sources of quality data, the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, and implementation of corrective and preventive actions.

Specifically,

1. The firm opened CAPA, C-8012-J, dated 7/24/08 to investigate sensor wire fractures. The CAPA was closed 7/23/09. The firm continues to receive complaints of sensor wire fractures in patients. The CAPA (C-8012-J) did not include the actions needed to correct or prevent recurrence of sensor wire fractures and other quality problems and the firm did not implement corrective and preventive actions.

2. The firm did not follow their CAPA procedure, SOP-140000 which requires corrective and preventative actions to prevent the recurrence of a potential nonconformity or other undesirable situation (C-8012-J).

Annotation: Promise to Correct by 3/8/2010

Reference: 21 CFR 820.100(b)

Relevance: CAPA is ineffective and not conducted per the firm's procedures.

Discussion with Management: Mr. Balo said he promise to correct and will provide a written response to FDA within 15 days.

OBSERVATION 3

Complaint handling procedures for complaints have not been implemented.

Specifically,

1. The firm's complaint procedure, SOP-140200 requires the firm to submit an Adverse Reaction and Device Defect Report to FDA within (b) (4) days of knowledge of any adverse reaction or injury to a patient. This report has not been submitted to FDA within (b) (4) days of an adverse reaction or injury.

2. The firm's complaint procedure, SOP-140200 requires the firm to initiate a customer complaint after receipt of a potential complaint. The firm is documenting multiple complaints of sensor wire breakage under one complaint number as exampled by 08-(b) (4).

Annotation: Promise to Correct by 2/12/2010

Reference: 21 CFR 820.198(a)

Relevance: The firm is not implementing their complaint procedure.

Discussion with Management: Mr. Balo said he promise to correct and will provide a written response to FDA within 15 days.

OBSERVATION 4

An individual medical device manufacturer report submitted per FDA Form 3500A did not contain in Block A the patient's age or date of birth.

Specifically, 7 out of 27 MDR reports reviewed and provided to FDA did not include the age of the patient as exampled by 3004753838-2010-00001, 0006, 00011, 00013, 00023, 00025 and 00027. This information is reasonably known to the firm.

Annotation: Promise to correct by 2/19/2010

Reference: 21 CFR 803.52(a) (2)

Relevance: Many patients are pediatric patients such as infants and small children and the use of this device on these patients is off-label. The MDRs do not capture this information. MDR reports are incomplete when submitted to FDA. Mr. Balo provided the (b) (4) tracking sheet which he said the MDRs have been sent to FDA on 1/29/10 and were received on 2/1/10, **Exhibit 39.**

Discussion with Management: Mr. Balo said he promise to correct and will provide a written response to FDA within 15 days.

OBSERVATION 5

An individual medical device manufacturer report submitted per FDA Form 3500A did not contain in Block B the date of report by the initial reporter.

Specifically, (b) (4) FDA-Form 3500A reports submitted to FDA during this inspection did not include the actual date of filing the report as exampled by:

1. MW 3004753838-2010-00001: Date of event was 1/5/09. The date of this report is 1/5/09.

2. MW 3004753838-2010-00010: Date of event was 4/21/09. The date of this report is 4/22/09.

3. MW 3004753838-2010-00073: Date of event was 12/29/08. The date of this report is 12/29/09.

Annotation: Promise to correct by 3/8/2010

Reference: 21 CFR 803.52(b) (4)

Supporting Evidence and Relevance: The reports to FDA inaccurately report the date the MDR being submitted by the initial reported (DexCom) to FDA as the date of the event. This was discussed several times with the firm and the firm continued to provide inaccurate dates.

Discussion with Management: Mr. Balo said he promise to correct and will provide a written response to FDA within 15 days.

OBSERVATION 6

Complaint handling procedures have not been implemented to ensure that all complaints are processed in a uniform and timely manner.

Specifically, the firm is not closing complaints in a timely manner as exampled by complaint 08-(b) (4). The complaint was opened on 9/30/08 for sensor wire breakage. The complaint was closed during this inspection on 1/22/2010.

Annotation: promise to correct by 3/8/2010

Reference: 21 CFR 820.198(a) (1)

Relevance: Complaints are not being closed in a timely manner.

Discussion with Management: Mr. Balo said he promise to correct and will provide a written response to FDA within 15 days.

OBSERVATION 7

Employees have not been adequately trained.

Specifically, the firm's employees (Dr. B.M., Director of Clinical Research and in-house medical officer and S.B, Technical Support Supervisor) failed to follow the firm's MDR reporting procedure, SOP-300024 after having talked with patients involving sensor wire breakage under the skin, redness, irritation and other conditions as exampled by complaint 09-(b) (4). The procedure requires the firm to prepare a Device Defect Report for any adverse reaction, side effect or sensitivity that is attributed to the device.

Annotation: promise to correct by 2/12/2010

Reference: 21 CFR 820.25(b)

Relevance: Employees are not adequately trained and are providing information to patients, which is in conflict with their procedures.

Discussion with Management: Mr. Balo said he promise to correct and will provide a written response to FDA within 15 days.

ATTACHMENTS

1. FDA-482 issued to Mr. Balo, dated 1/11/10
2. FDA-482 issued to Mr. Balo, dated 2/1/10
3. FDA-483 issued to Mr. Balo, dated 2/8/10
4. CDRH memo dated 8/31/09
5. CDRH Memo dated 9/3/09
6. CR 427960

EXHIBITS

1. Instructions for Use, DexCom STS Continuous Glucose Monitoring System
2. User's Guide, DexCom STS Continuous Glucose Monitoring System
3. Quick Start Guide DexCom Continuous Glucose Monitoring System
4. Limited Warranty Card
5. Training Worksheet DexCom CGM
6. Tips For Using Seven Plus CGM DexCom
7. Your Patient's G.P.S (Glucose Protection System) Brochure
8. Your Personal G.P.S. (Glucose Protection System) Brochure
9. DexCom 2009 Continuous Glucose Monitoring (CGM) Coding Reference
10. Is Continuous Glucose Monitoring Right For You Brochure
11. CD Copy of DexCom Seven Sensor Kit Labels
12. CD copy of DexCom Seven Plus Starter Kit labels
13. CD copy of DexCom Website www.dexcom.com
14. Listing of the Board of Directors and short bio of each person listed
15. DexCom 2008 Annual Report
16. Distributor list
17. Product list
18. Current price lists
19. Total STS shipments and inventory list
20. Organizational Chart
21. Floor plan
22. Complaint SOP
23. CD of complaints
24. Emails from Dr. Matsubara
25. MDRs and Complaints for sensor wire fractures
26. Memo from Mr. Balo
27. Complaint 08-2682

28. Trouble Shooting Guide
29. Trouble Shooting Guide on CD
30. MDR SOP
31. CAPA SOP
32. CAPA C-8012-J
33. CAPA C-9005-G and associated studies
34. (b) (4) Investigation
35. CES Job Description
36. CES employee list
37. Correction and Removals SOP
38. Memo from Mr. Balo regarding no field corrections planned
39. (b) (4) tracking sheet for MDRs to FDA
40. Memos of complaint investigations

Trudy R. Papson, Investigator