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SUMMARY

This was a pre-announced inspection of a class II medical device manufacturer of electrotherapy equipment. This inspection was conducted in accordance with C.P. 7382.845 Inspection of Medical Device Manufacturers and issued under LOS-DO FY 2009 work plan, FACTS Assignment ID #671344. PACs 82845A, 82012, 81011 and 81845R were covered and profile codes ELE, MTL and PRF were reported.

The previous FDA inspection of 03/1997 was a compliance follow-up inspection to Warning Letter (WL-30-6) issued to the firm on 4/17/96. The inspection was classified "VAI" and cited the firm for: a) not trending quality data, b) lacked a written investigation into significant component failures in distributed devices, c) lacked a formally designated unit to review, evaluate and maintain complaints, d) audits were not performed by appropriate personnel and d) no device history records were maintained for muscle stimulators.

The previous FDA inspection conducted in 09/2002 was classified "VAI". The firm was cited for a continued lack of a quality assurance program, to collect and analyze quality data and to implement corrective and preventive actions, and continued to assign individuals to audit the areas for which they are responsible. The firm lacked written procedures for purchasing controls and had deficient MDR procedure.

The current inspection found the firm continues to operate without a quality system, no quality procedures, no quality policy, no quality plan, no MDR procedure and no servicing procedures. The firm does not conduct management reviews, internal quality audits, trending of service reports, and training on a quality policy. The firm failed to report MDR reportable events to FDA. Equipment used for finished device release testing was out of calibration and results of complaint investigations were not documented.

The firm's President/CEO stated at the close of the inspection that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

DOC 393850 for the "SynchroSonic US/54" was collected to document Quality System Regulation deficiencies and interstate commerce. There were no refusals.

ADMINISTRATIVE DATA

Inspected firm:	Amrex-Zetron Inc.
Location:	641 E Walnut St Carson, CA 90746-1227
Phone:	310-527-6868
FAX:	310-366-7343
Mailing address:	641 East Walnut Street Carson, CA 90746
Hours of Operation:	(b) (4)
Facility Size:	
Website:	http://www.amrex-zetron.com
Dates of inspection:	10/21/2008, 10/23/2008, 11/3/2008
Days in the facility:	3
Participants:	Selene T. Torres, Investigator

On 10/21/08, I showed my credentials and issued a FDA-482 Notice of Inspection to George L. Bell, President/CEO (b) (4) of Amrex-Zetron, Inc. Mr. Bell identified himself as the most responsible person at the firm.

On 11/03/08, I showed my credentials and issued a FDA-482 Notice of Inspection to Jeffery A. Maddy, Operations Support who stated Mr. Bell was not in the office yet and he was the most responsible person available. A second FDA-482 was issued due to a break in the inspection.

On 11/03/08, Mr. Bell signed an Affidavit and I issued a FDA-483 Inspectional Observations to George L. Bell, President/CEO. During discussion with management the FDA-483 was modified and a second FDA-483 was issued to George L. Bell, President/CEO, dated 11/03/08.

HISTORY
Mr. Bell stated the firm was established in 1935 to manufacture medical devices as two firms known as Amrex and Zetron Electronics. He stated he became President of the company in 1979 when the firm was incorporated in the State of California as Amrex-Zetron, Inc.

The previous FDA inspection conducted in 03/1997 was a compliance follow-up inspection to a Warning Letter (WL-30-6) issued to the firm on 4/17/96. This follow-up FDA inspection was classified "VAI". The inspection cited the firm for: a) not trending quality data, b) lacking a written investigation into significant component failures in distributed devices, c) lacking a formally designated unit to review, evaluate and maintain complaints, d) audits were not performed by appropriate personnel and d) no device history records were maintained for muscle stimulators.

The previous FDA inspection conducted in 09/2002, was also classified "VAI". The firm was cited for continuing to lack a quality assurance program to collect and analyze quality data and to implement corrective and preventive actions, and continued to assign individuals to audit the areas for which they are responsible. The firm lacked written procedures for purchasing controls and had deficient MDR procedures.

Since the previous FDA inspection conducted in 09/2002 Mr. Bell stated the firm has had a staff reduction from (b) (4) employees to (b) (4) employees. (b) (4)
(b) (4)

Mr. Bell told me the firm has not initiated any recalls. He stated the firm has no parent corporation or subsidiaries and has no other storage locations.

The firm is registered as a medical device manufacturer under registration #(b) (4).

Future FDA correspondence should be addressed to:

George L. Bell, President/CEO
Amrex-Zetron, Inc.
641East Walnut Street
Carson, CA 90746

INTERSTATE COMMERCE
Mr. Bell stated the firm ships approximately (b) (4) % of their medical devices into interstate commerce. DOC 595850 for the US/54 was collected to document interstate commerce and QSR deficiencies (Attachment).

JURISDICTION
Amrex-Zetron, Inc. designs, develops, manufactures, distributes and services Class II electrotherapy equipment. The firm's product line includes therapeutic ultrasound, electrical stimulators, and accessories. The firm utilizes the brand names "Amrex", "Z-Stim", "Advanteq", "Flextro", and "SynchroSonic".

Product brochures (**Exhibit 1**), an Electrotherapy Equipment Catalogue (**Exhibit 2**), an Accessory Price List (**Exhibit 3**), DVDs for the stimulators (**Exhibit 4**) and ultrasound (**Exhibit 5**) and labeling for the SynchroSonic US/54 (**Exhibit 6**) were provided.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
George L. Bell, President/CEO is listed in the firm's FDA registration as the Official Correspondent. Mr. Bell has ultimate responsibility in the company. His authority is documented in the firm's Organizational Chart (**Exhibit 7**) dated 07/24/08, approval signature in the unapproved, unreleased Quality Manual Rev. 1 dated 05/11/04 (**Exhibit 8, pages 6, 9 and 13**). Mr. Bell stated he started with the company in 1974 when it was Amrex and Zetron Electrotherapy. He stated he has been the President of Amrex-Zetron, Inc. since approximately 1980. He told me he is responsible for administration, corporate management, manufacturing and all aspects of the company. He stated he has the ultimate responsibility in the company and is the controlling share holder. All employees report directly or indirectly to Mr. Bell. Mr. Bell provided the tour of the facility with Mr. Maddy and was present the first and last days of the inspection.

Paul Elliott, V.P. Manufacturing was not present during this inspection. Mr. Bell stated Mr. Elliott is usually responsible for the firm's quality system but has been out (b) (4) (b) (4) . Mr. Bell stated Mr. Elliott wrote the User Guides. Mr. Elliott is the firm's Management Representative. In his absence, Mr. Maddy is handling his responsibilities.

Jeffrey A. Maddy, Operations Support has been with the company since June 2008. Mr. Maddy stated he is responsible for support operations and manufacturing, documentation, quality and assisting me with this inspection. Mr. Maddy provided all documents and photos during this inspection and was present all days. Mr. Maddy reports to Mr. Bell as shown on the Organizational Chart (**Exhibit 7**).

(b) (6) Technician described the serviced device release testing processes. He is responsible for servicing the firm's medical devices and conducting release testing. He reports to Mr. Bell as shown on the Organizational Chart (**Exhibit 7**).

FIRM'S TRAINING PROGRAM
See Inspectional Observation #2.

MANUFACTURING/DESIGN OPERATIONS

Registration and Listing
The firm's registration as a medical device manufacturer (Registration #(b) (4)) and device listing were observed current.

Management Controls
See Inspectional Observations 1-5.

Corrective and Preventive Actions
See Inspectional Observations 3, 6, 7, 10, 11 for observations related to CAPA and Medical Device Reporting. The firm has not had any recalls and has no established recall procedure.

Production and Process Controls
I covered the serviced finished device release testing processes for ultrasound equipment. See Inspectional Observations 8-10.

MANUFACTURING CODES
(b) (4)

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

This FDA-483 was modified during discussion with management.

OBSERVATION 1

Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.

Annotation: None

Reference: 21 CFR 820.20

Supporting Evidence and Relevance: The firm's President/CEO (b) (4) (b) (4) has not implemented a quality system as observed in the current inspection and previous FDA inspections.

Discussion with Management: Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, the Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 2

Management with executive responsibility has not ensured that the quality policy has been fully implemented and maintained at all levels of the organization.

Specifically:

1. Employees have not been made aware that the firm has a Quality Policy.
2. (b) (4) employee (including the President, Operations Support, Director of Manufacturing and three Production Employees) training records show employees have not been trained on a Quality Policy.
3. The Quality Policy is maintained in the firm's Quality Manual dated 05/11/2004 which has not been approved or released.

Annotation: None

Reference: 21 CFR 820.20(a)

Supporting Evidence and Relevance: Medical device manufacturers are required under the Quality System Regulations to establish a Quality Policy throughout their organization; **Exhibit 8, page 13 and Exhibits 9-12.**

Discussion with Management: I asked Mr. Maddy if the firm had implemented the Quality Policy documented in the unapproved and unreleased Quality Manual (**Exhibit 8, page 13**). He stated they had not. I reviewed (b) (4) employee training records Mr. Maddy provided to me, for which he stated they were the complete training records. (b) (4) of the (b) (4) employee training files reviewed (**Exhibits 9-12**) showed the employees had not been trained on their Quality Policy. The employee training files show employees are trained on each device model type. There were no training records for Mr. Maddy and Mr. Bell. The observation was disclosed to Mr. Maddy during the inspection.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 3

Quality system procedures were not established and implemented.

Specifically, Amrex-Zetron, Incorporated ISO 13485 Quality Manual Revision 1 dated 05/11/04 has not been approved, released or implemented and your firm has no other documented quality procedures.

Annotation: None

Reference: 21 CFR 820.20(e)

Supporting Evidence and Relevance: The firm has not established Quality System procedures required by the Quality System Regulations. The firm's only quality document includes ISO 13485 Quality Manual, Rev. 1 dated 05/11/04 which has never been approved or implemented; **Exhibit 8**.

Discussion with Management: I asked Mr. Maddy and Mr. Bell if I could review the firm's Quality Manual and quality procedures. Mr. Maddy provided me with a copy of Amrex-Zetron, Inc. ISO 13485 Quality Manual, Rev. 1 dated 05/11/04 (**Exhibit 8**) which has never been approved or implemented. Mr. Maddy told me the Quality Manual is the firm's only procedure (b) (4) . I reconfirmed during the next day of the inspection that the firm had no approved Quality Manual or procedures and Mr. Maddy stated I was correct. My observation was disclosed to Mr. Maddy during the inspection.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, the Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 4

Management reviews were not conducted at defined intervals.

Specifically, the firm has not conducted a management review in (b) (4) years. The last management review was held on (b) (4)

Annotation: None

Reference: 21 CFR 820.20(c)

Supporting Evidence and Relevance: The firm is required to conduct Management Reviews to evaluate their Quality System and Quality Policy at defined intervals. The firm has not conducted a Management Review in (b) (4) ; **Exhibits 13-17.**

Discussion with Management: I asked Mr. Maddy for certification of the firm's Management Reviews for the last 4 years. Mr. Maddy provided me with certification of Management Reviews dated (b) (4) , (b) (4) , (b) (4) , (b) (4) , and (b) (4) (**Exhibits 13-17**). He stated these were the only Management Reviews the firm has conducted. My observation was disclosed to Mr. Maddy during the inspection.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 5

Quality audits were not conducted to verify that the quality system is effective in fulfilling your quality system objectives.

Specifically, your firm does not conduct internal quality audits.

Annotation: None

Reference: 21 CFR 820.22

Supporting Evidence and Relevance: The firm is required to conduct internal quality audits.

Discussion with Management: I asked Mr. Maddy if I could review the firm's audit schedules and plans for the last 4 years. Mr. Maddy stated he would have to call Mr. Elliott and verify where these documents were located. On the next day of the inspection, Mr. Maddy told me the firm had not conducted quality audits for (b) (4) years and that they did not have any audit schedules or plans. The observation was disclosed to Mr. Maddy during the inspection.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 6

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, you received a complaint on 07/22/08 that a patient using one of your ultrasound units was injured resulting in visual skin and tissue damage. This incident was not reported to FDA.

Annotation: None

Reference: 21 CFR 803.50(a)(1)

Supporting Evidence and Relevance: The firm is required to submit MDRs to FDA in events where the device may have caused serious injury; **Exhibit 18.**

Discussion with Management: I reviewed (b) (4) complaints received since the previous FDA inspection conducted in 09/2002. (b) (4) of the (b) (4) complaints I reviewed reported on 07/22/08 that a patient using one of Amrex-Zetron Inc.'s ultrasound units was injured

resulting in visual skin and tissue damage (**Exhibit 18, pages 1 and 4**). Mr. Bell stated when he contacted the doctor, the doctor told him that he only used Amrex equipment. This incident was not reported to FDA. The firm has not implemented a MDR procedure. My observation was discussed with Mr. Maddy during the inspection.

At the close of the inspection, Mr. Bell stated that this complainant (b) (4). He stated he contacted the physician to get more information, but none was provided other than the physician did use Amrex devices (b) (4) (b) (4). Mr. Bell stated he did not know the device model or serial number for the complaint and he could not trace his records because the device was likely purchased through a distributor.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, the Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 7

Records of complaint investigations do not include the results of the investigation.

Specifically, (b) (4) complaints (complaint (b) (6) dated 07/22/08 and (b) (6) dated 01/22/04) ~~reviewed were not thoroughly investigated.~~ did not include the results of the investigation.

Annotation: None

Reference: 21 CFR 820.198(e)(6)

Supporting Evidence and Relevance: Results of complaint investigations are not always documented in the complaint record; **Exhibits 18 and 19**.

Discussion with Management: This observation was modified during discussion with management. See "Additional Information" section of this report. During the close out meeting Mr. Bell told me that in regards to complaint (b) (6) dated 01/22/04 (**Exhibit 19**) the unit is contraindicated to be used around metal units which could cause potential leakage. He stated this unit was returned and evaluated and was within specification and that the user was likely using it improperly. I told Mr. Bell that the fact that the unit was returned and tested should have been documented in the complaint record. He agreed.

In regards to complaint (b) (6) dated 07/22/08 (**Exhibit 18**), Mr. Bell told me he spoke with the doctor that used the Amrex equipment on the complainant. Mr. Bell told me the doctor told him he could not talk to him about it. The doctor told him he only uses Amrex equipment. I asked Mr. Bell if he could have checked their inventory to see which units and serial numbers were sold to the doctor so they could evaluate DHRs and look to see if there were other complaints with this model. Mr. Bell stated they could not do this because the equipment was probably purchased from a distributor. Mr. Bell agreed this should have been documented in the complaint record because the firm could not conduct any further investigation without the model number or serial number.

OBSERVATION 8

Servicing procedures have not been established.

Specifically, the firm has no documented servicing procedures.

Annotation: None

Reference: 21 CFR 820.200(a)

Supporting Evidence and Relevance: The firm conducts service on their electrotherapy equipment. The firm is required to have documented servicing procedures; **Exhibits 20 & 21.**

Discussion with Management: During the inspection, Mr. Maddy provided me with a list of the firm's current in-house service log (**Exhibit 20**). I reviewed 11 service reports as per Binomial Staged Sampling Plan, Table 1, row A. I asked Mr. Maddy if the firm had serving procedures and he stated they did not. (b) (6) stated he knew what the specifications for release were and that is how he determines release criterion after servicing and showed me on a DHR (**Exhibit 21**). The observation was disclosed to Mr. Maddy during the inspection that the firm was required to have documented servicing procedures.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 9

Procedures to ensure that equipment is routinely calibrated were not established and implemented.

Specifically, your firm has not established procedures for equipment calibration. The (b) (4) scope SS-6122 (calibration due 05/18/08) and (b) (4) Meter UPM-DT-10 (calibration due 06/15/08) used for finished device release testing were not within calibration dates.

Annotation: None

Reference: 21 CFR 820.72(a)

Supporting Evidence and Relevance: The firm is conducting finished device release testing with equipment that is out of calibration; **Exhibits 21-23.**

Discussion with Management: I asked Mr. Maddy if we could go to the servicing area of the facility. While in the servicing area, (b) (6) , Technician described the servicing testing and release process. He stated that for release of ultrasound equipment, the firm conducts calibration checks with the UPM-DT-10 (**Exhibit 22**) and does all functions checks for frequency, pulse width and voltage with the MS322 (**Exhibit 23**). He stated this is documented on a service record (**Exhibit 21**). I observed the calibration stickers for both equipment units were out of calibration. Mr. Maddy took the photos of the calibration stickers and provided me with a copy (**Exhibits 22-23**). My observation was disclosed to Mr. Maddy during the inspection.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 10

Service reports were not analyzed following appropriate statistical methods.

Specifically, your firm services your medical devices, such as ultrasound and muscle stimulators. You have not analyzed service reports for trends.

Annotation: None

Reference: 21 CFR 820.200(b)

Supporting Evidence and Relevance: The firm conducts service on their equipment on a regular basis. These service reports are not statistically analyzed to determine if they are potential CAPA sources; **Exhibit 20.**

Discussion with Management: I reviewed the log sheets for the firm's current service tickets (**Exhibit 20**) as well as a list of previously serviced tickets. I asked Mr. Maddy if the firm trended the service reports. Mr. Maddy stated he would confirm with Mr. Bell and Mr. Elliott. The next day of the inspection, Mr. Maddy stated the firm does not do any trending at all. My observation was disclosed to Mr. Maddy during the inspection.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

OBSERVATION 11

Written MDR procedures have not been developed and implemented.

Specifically, the firm has no MDR procedures.

Annotation: None

Reference: 21 CFR 803.17

Supporting Evidence and Relevance: Medical device manufacturers are required to have defined, documented and implemented MDR procedures. The firm has no implemented MDR procedure; **Exhibit 8**.

Discussion with Management: During the inspection I asked Mr. Maddy if the firm had quality procedures and a MDR procedure. He stated they only had a Quality Manual

(**Exhibit 8**) (b) (4) but no other quality procedures. The Quality Manual is not approved or implemented. I discussed with Mr. Maddy that the firm was required to have a MDR procedure. I reviewed one complaint which was MDR reportable but not reported to FDA. See Inspectional Observation #6.

Mr. Bell chose to provide one comment for all observations at the close of the inspection. At the close of the inspection, Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. He stated they would respond in writing within 2 weeks.

REFUSALS
There were no refusals.

GENERAL DISCUSSION WITH MANAGEMENT
Mr. Bell and Mr. Maddy were present at the close of the inspection. I explained to Mr. Bell and Mr. Maddy that as a medical device manufacturer, their firm had the option to annotate their FDA-483 and I explained the annotation options. I issued the FDA-483 Inspectional Observations and I notified Mr. Bell and Mr. Maddy that "The conditions listed may, after further review by the Agency, be considered to be violations of the Food, Drug and Cosmetic Act. Legal sanctions, including seizure, injunction, civil money penalties and prosecution, are available to FDA if establishments do not voluntarily correct serious conditions."

During discussion with management, the FDA-483 Inspectional Observations was modified. The underlying citation and description for Observation #7 was modified.

I again asked Mr. Bell if he would like to annotate the observations. Mr. Bell chose to provide one comment for all observations at the close of the inspection. Mr. Bell stated that the firm had undergone a reduction in work force and they would leave the response to the FDA-483 observations open pending re-staffing to make proper corrections. I advised Mr. Bell the firm could respond in writing at the address listed at the top of the FDA-483 to the Los Angeles District Director, Alonza Cruse. He and Mr. Maddy stated they would respond in writing within 2 weeks.

ADDITIONAL INFORMATION
There were breaks in the inspection due to scheduling conflicts and to allow the firm to contact Mr. Elliott, who oversees the firm's Quality Program. (b) (4)
(b) (4)

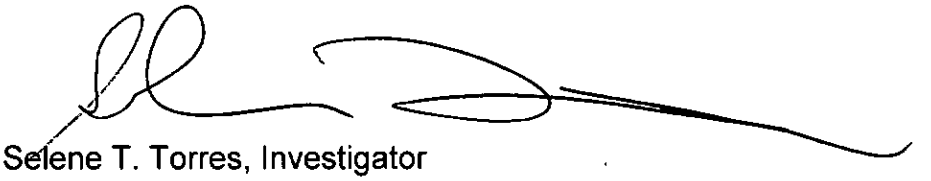
The underlying citation and description for Observation #7 was modified during discussion with management. The original FDA-483 and a copy of the modified FDA-483 were submitted as attachments to this EIR.

SAMPLES COLLECTED
DOC 393850 for the US/54 Ultrasound was collected to document interstate commerce and Quality System Regulation deviations.

EXHIBITS COLLECTED
1. Marketing brochures
2. Catalogue
3. Accessory list
4. Stimulator DVD
5. Ultrasound DVD
6. US/54 labeling
7. Organizational chart
8. Quality Manual Rev. 1 dated 05/11/04.
9. Training Record Employee (b) (4).
10. Training Record Employee "PE".
11. Training Record Employee (b) (4).
12. Training Record Employee .
13. Management Review dated 06/2000.
14. Management Review dated 09/2000.
15. Management Review dated 01/2001.
16. Management Review dated 01/2001.
17. Management Review dated 10/2002.
18. Compliant (b) (6) dated 07/22/08.
19. Complaint (b) (6) dated 01/22/04.
20. Service log dated 10/21/08.
21. Service DHR for repair tag (b) (4).
22. Photo of Calibration sticker for UPM-DT-10 taken 10/23/08.
23. Photo of Calibration sticker for MS322 taken 10/23/08.

ATTACHMENTS

1. Copy of FDA-482 Notice of Inspection issued to George L. Bell, President/CEO, dated 10/21/08.
2. Copy of FDA-482 Notice of Inspection issued to Jeffrey L. Maddy, Operations Support, dated 11/03/08.
3. FDA-483 Inspectional Observations issued to George L. Bell, President/CEO, dated 11/03/08.
4. Copy of modified FDA-483 Inspectional Observations issued to George L. Bell, President/CEO dated 11/03/08.
5. Copy of affidavit signed by George L. Bell, President/CEO, dated 11/03/08 (original submitted with DOC 595850).
6. Copy of Collection Report for DOC 595850 for US/54 Ultrasound.



Selene T. Torres, Investigator