Magellan Diagnostics, Inc. 10/23/17

Medical Devices and Radiological Health, Division 1 East
1 Montvale Ave
Stoneham, MA 02180

WARNING LETTER
CMS #532743

VIA UNITED PARCEL SERVICE

October 23, 2017

Amy M. Winslow
President and Chief Executive Officer
Magellan Diagnostics, Inc.
101 Billerica Avenue, Bldg. 4
North Billerica, MA 01862-127
email: Amy.Winslow@magellandx.com

Dear Ms. Winslow:

During an inspection of Magellan Diagnostics, Inc., located in North Billerica, Massachusetts on May 10, 2017 through June 29, 2017, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures the LeadCare Blood Lead Testing System, the LeadCare II Blood Lead Testing System, the LeadCare Ultra Blood Lead Testing System, and the LeadCare Plus Blood Lead Testing System (collectively, the

"LeadCare Systems"). Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

Our inspection revealed that your firm's LeadCare II and LeadCare Ultra Systems are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), **(b)(4)**. The LeadCare II and LeadCare Ultra Systems are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce these devices into commercial distribution, in that a notice or other information respecting the modifications to each of these devices was not provided to FDA, as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3). Specifically,

1. Your firm made significant labeling and design changes to the LeadCare II System after FDA's clearance of that device on October 6, 2005. For example, the proposed labeling submitted to FDA as part of the premarket notification (510(k)) for the LeadCare II System at the time of the device's clearance describes the readiness of the sample for analysis immediately after mixing of the treatment reagent with the blood sample. However, your firm made a significant change by adding to the device labeling an instruction that users allow the blood-treatment reagent mixture to stand for 4 hours at room temperature prior to analysis for venous blood samples that are shipped or rocked. Your firm added this 4-hour incubation time to reduce the risk of the LeadCare II System underestimating lead values for these venous blood samples. This change could significantly affect the safety or effectiveness of the device and requires submission of a new 510(k). Your firm did not notify FDA of this significant change before introducing the modified LeadCare II System into commercial distribution, and FDA has not received a new 510(k) for the device to date.

2. Your firm made significant labeling and design changes to the LeadCare Ultra System after FDA's clearance of that device on August 20, 2013. For example, the proposed labeling submitted to FDA as part of the 510(k) for the LeadCare Ultra System at the time of the device's clearance describes the readiness of the sample for analysis immediately after mixing of the treatment reagent with the blood sample. However, your firm made a significant change by adding to the device labeling an instruction that users implement a minimum 24-hour incubation time for the blood-treatment reagent mixture prior to analysis. Your firm made this change to reduce the risk of the LeadCare Ultra System underestimating the lead values of some blood samples. This change could significantly affect the safety or effectiveness of the device and requires submission of a new 510(k). Your firm did not notify FDA of these significant changes before introducing the modified LeadCare Ultra System into commercial distribution.

(b)(4)

For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency. 21 CFR § 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for a device is described on the Internet at **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm)**. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

We also note that, during the time your 510(k) for the LeadCare Plus System was pending, your firm added to the proposed labeling an instruction that users implement a minimum 24-hour incubation time for the blood-treatment reagent mixture prior to analysis. While your firm submitted proposed labeling to FDA that reflected this change, your firm described revisions made to the proposed labeling as “minor updates” and did not update your 510(k) submission to explain the significance of this change. For example, your firm should have identified this significant design change as a difference in the technological characteristics of the predicate device and the LeadCare Plus device that was under review in your 510(k) submission.

This inspection also revealed that your firm’s LeadCare Systems are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at 21 CFR Part 820.

We received a response dated July 21, 2017 from Ms. Amy M. Winslow, President & CEO of Magellan Diagnostics, Inc., concerning the investigator’s observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to the firm at the conclusion of the inspection. We acknowledge that the response states that **(b)(4)**, that your firm’s current QA/RA management will be **(b)(4)**, and that **(b)(4)** will provide a comprehensive quality system training to your firm’s personnel. We received an additional response from your firm dated September 21, 2017, and will evaluate this response along with any other written material provided in response to the violations cited in this letter.

We further address your firm’s July 21, 2017 response below, as applicable, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Design validation failed to ensure that devices conform to defined user needs and intended uses, as required by 21 CFR 820.30(g). For example:

a. At the time of clearance, the labeling of the LeadCare II and LeadCare Ultra Systems allowed for the immediate analysis of whole blood samples after thoroughly mixing the blood/treatment reagent mixture and after storage of that mixture for up to 48 hours at room temperature or up to 7 days if stored refrigerated. The labeling of the LeadCare Plus System, at the time of clearance, allowed for the analysis of venous whole blood samples after storage of the blood/treatment reagent mixture for 24-48 hours at room temperature and up to 3 days if stored refrigerated. However, your firm did not provide any documents showing that your original validation studies tested under these actual use conditions and that these studies support the blood/treatment reagent mixture stability claims made in your labeling.

b. Your firm released the LeadCare Ultra System for commercial distribution in September 2013 after becoming aware of the potential for falsely low and falsely high test results for samples incubated less than 24 hours in the treatment reagent. For example, your firm’s stability study for the treatment reagent provided during the inspection, entitled Blood in Treatment Reagent Stability Study Protocol-VP #113, Part 1, dated 09/05/2013, concluded that there was a “reproducible trend of increased [lead] signal with increased Sample/Treatment Reagent incubation time” as well as the possibility for “false lows or false highs”; and your firm’s stability study for the treatment reagent, entitled Blood and Treatment Reagent Stability Study-VP #113, Part 2, dated 09/10/2013, stated that “Sample/Treatment Reagent Preparations **(b)(4)**.”

c. Your firm released the LeadCare Ultra System for commercial distribution after some results obtained in your firm’s stability study failed to meet the original acceptance criteria documented in Magellan Diagnostics Design Control Document entitled, “Blood and Treatment Reagent Stability Study-VP # 113, Part 2, Rev 1”, dated 9/10/13, which were **(b)(4)**. The final report for that study recommends expanding the acceptance criteria in the study protocol

and to pass data **(b)(4).**

d. On November 24, 2014, your firm sent a Notice to Customers letter instructing customers to incubate the blood-treatment reagent mixture for at least 24 hours to prevent underestimation of the lead concentration of blood samples on the LeadCare Ultra System. On November 4, 2016, your firm sent a Notice to Customers letter instructing customers to incubate venous blood/treatment reagent mixtures for samples that may have come in contact with the rubber stopper of a blood collection tube for at least 4 hours to prevent underestimation of the lead concentration of blood samples on the LeadCare II System. Your firm failed to validate the effectiveness of these minimum incubation times for LeadCare Ultra (24 hours) and for LeadCare II (4 hours). These minimum incubation times also do not allow for the immediate analysis needs of some healthcare providers for their patients, as reported in Complaint Cases #00112233, dated 10/28/2014, and #00119771, dated 09/09/2015.

We have reviewed your firm's response and conclude that it is not adequate. Your response states that you have initiated Corrective Action Plans CAR-1223 and CAR-1229 and that you have conducted studies to verify that the 24-hour incubation of the blood/treatment reagent mixture was an effective mitigation to prevent the underestimation of the lead concentration in certain blood samples. Your response acknowledges, however, that the studies were not well documented. Your response further states that in order to re-establish venous blood as an acceptable sample type, your firm is working to complete and document further validations and that your firm will assess its existing design validation studies to determine if there are failures to ensure that devices conform to defined user needs and intended uses other than those identified in the FDA 483. Additionally, your response states that **(b)(4)** by the end of the 2017 calendar year. Your response also states that **(b)(4)** will provide training to your employees, including training on validation protocols, by January 2018. However, you have not provided supporting documentation for your firm's corrective actions, including documentation to support that you have performed adequate validations.

2. Failure to ensure that design validation includes risk analysis that is complete and adequate, pursuant to 21 CFR 820.30(g). Specifically, your Risk Analysis Procedure, SOP 159, Rev 04, requires product risk analysis to be updated based on post-production information. However, your firm failed to update, identify, and/or adequately evaluate the risks to patients from falsely low results for the LeadCare Ultra, LeadCare II, and LeadCare Plus Systems. For example:

a. The LeadCare Ultra Risk Analysis, entitled Risk Analysis-Lead Care, Rev 10, dated 05/31/2013, did not list false negative or false low results as a potential hazard or risk. Further, this risk analysis was not updated based on your firm's studies entitled "Blood in Treatment Reagent Stability Study Protocol-VP #113, Part 1", dated 09/05/2013, which concluded that there was a reproducible trend of increased lead signal with increased sample/treatment reagent incubation time which can create false low or false high results; and "Blood and Treatment Reagent Stability Study-VP #113, Part 2", dated 09/10/2013, which also found an increased lead signal with increased incubation time. In addition, this LeadCare Ultra Risk Analysis was not updated after your firm became aware in August 2014 of customer complaints of discrepancies in results obtained from the LeadCare Ultra System.

b. The LeadCare II Risk Analysis, entitled Risk Analysis-Lead Care II, Rev 6, dated 09/08/2005, included a hazard of "Erroneous Result, False Low." However, the analysis of this hazard was not updated based on customer complaints regarding falsely low results to reflect the likelihood of harm with respect to venous blood samples.

c. The Risk Management Plan, LeadCare Plus Blood Lead Testing System, Rev 5, dated 09/18/2014, identified the hazard of "**(b)(4)**", with a severity classification of **(b)(4)** (defined as "[f]ailures or **(b)(4)** that **(b)(4)**") and a probability of **(b)(4)** (defined as "**(b)(4)**"). This hazard was not updated based on post-production information.

We reviewed your firm's response and conclude that it is not adequate. Your response states that you have initiated Corrective Action CAR-1224 and that your firm will independently create a comprehensive Failure Mode and Effects Analysis (FMEA) template to be used for assessing risks for the LeadCare Systems family to ensure the risk analysis for each device includes all shared failure modes. In addition, your response states that your firm will reassess all elements of its risk assessment documents for the LeadCare Systems and revise them to eliminate any identified gaps. However, your response does not include updates to your Risk Analysis for the LeadCare Ultra, LeadCare II, and LeadCare Plus Systems, including updates in accordance with Risk Analysis Procedure, SOP 159, Rev 04, which requires that product risk analysis be updated based on post-production information. In addition, you have not provided supporting documentation for your firm's corrective actions.

3. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, pursuant to 21 CFR 820.198(a). Specifically,

a. Your firm has not adequately established procedures that define how your firm's Product Support employees uniformly evaluate information to determine if it represents a complaint or a non-complaint customer interaction. For example, your firm's Complaint Procedure, SOP #107, Rev 09 and 21 CFR 820.3(b) define a complaint as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution." However, Support Request Case # 00103942 involved a customer describing particulate matter in the treatment reagent, and Support Request Case # 00122401involved a customer describing variation in the results obtained on the LeadCare Plus and the results obtained using another analyzer. However, your firm identified these communications as "Support Request/Help desk" case types and did not provide documentation that your firm evaluated them as complaints or evaluated whether they represent events that must be reported to FDA as medical device reports (MDRs) under 21 CFR Part 803.

b. Complaint Cases #'s 00114483 and 00126813, are examples of complaints describing low results obtained using the LeadCare Ultra System or LeadCare II System in comparison to results obtained using another method. Customer Complaint Cases #s 00110311, 00117184, and 00120173 are examples of complaints describing discrepancies in test results obtained for the same sample using one of the LeadCare Systems. Your firm's Complaint Procedure, SOP #107, Rev 09, requires that any complaint pertaining to incorrect results must immediately be reviewed for MDR reporting. However, the "MDR Chart for Complaints" section of the case files for these 5 complaints is blank, and your firm provided no documentation showing how these complaints were evaluated according to your firm's Complaint Procedure to determine whether an MDR was required.

c. Your firm has not established procedures that define how cases originally categorized as customer support requests are uniformly entered by employees into your firm's electronic **(b)(4)** system and uniformly evaluated to ensure the information will be accurately processed into the **(b)(4)**, if the support request case is subsequently determined to constitute a complaint for which an investigation may be necessary. For example, during the inspection, your firm's Director of Quality Assurance and Regulatory Affairs explained that your firm had been unable to determine how to convert a customer support request into a customer complaint in the **(b)(4)** system.

d. Your firm did not follow your Customer Complaint Procedure, SOP #107, Rev. 9, with respect to the following three complaints, which remained open after **(b)(4)** days from receipt of the complaint, without documented justification: Complaint Cases #'s 00124439 (open 122 days), 00127556 (open 109 days), and 00124108 (open 195 days).

We reviewed your firm's response and conclude that it is not adequate. Your response states that you have initiated Corrective Action Plan CAR-1225 and that your firm will be conducting a retrospective review of all complaints logged since July 2015, including those that are classified as Support Request/Help Desk case types, by October 2017. However, you have not provided documentation demonstrating that evaluations and/or investigations of all complaints noted in the above examples were completed. Further, your response states that your **(b)(4)**, the **(b)(4)**, and the **(b)(4)** document management system in order to determine when CAPA and complaint investigations are warranted. Please provide supporting documentation of the updates to this process as they are complete.

4. Failure to establish corrective and preventive action procedures, pursuant to 21 CFR 820.100(a). Specifically, your firm has not adequately implemented Corrective and Preventive Action Procedure, SOP 128, Rev 6, which requires effectiveness verification, defined as a "documented process to establish that the action accomplishes the intended objective and is proven to be effective", before CAR closure. For example, CAR 108 was opened to investigate the underestimation of lead concentration readings from the LeadCare Ultra System. As part of your corrective action, your firm issued a Notice to Customers, dated 11/24/2014, instructing them to incubate the blood-treatment reagent mixture for at least 24 hours. Your firm received customer complaints documented in Complaint Cases #00116937 (reported low LeadCare Ultra results by customer not using 24-hour incubation time) and #00132411 (reported low LeadCare Ultra results when using the 24-hour incubation time) after the customer notification, however, the CAR was closed on 03/21/2017 despite the lack of verification that the action was effective.

We reviewed your firm's response and conclude that it is not adequate. Your response states that you initiated Corrective Action Plan CAR-1226 and that, by calendar year, Q1 2018, your firm will conduct a retrospective review of all closed CAPAs generated from July 2015 to present to ensure each CAPA is effective and includes objective evidence verifying effectiveness. Your response also states that your firm will reassess how CAPAs are issued, as part of remediation actions. Further, your response states that following your **(b)(4)**, a detailed Comprehensive Priority Action Plan will identify target completion dates for activities and documents requiring remediation. However, you have not provided supporting documentation for your firm's corrective actions.

5. Failure to establish procedures for identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, pursuant to 21 CFR 820.30(i). Specifically, your firm's Engineering Change Order Procedure SOP #123, Rev 01, was not followed and did not assure that appropriate validation/verification occurred for the design changes implemented by your firm to add a minimum incubation time to the test procedure for the LeadCare II, LeadCare Ultra, and LeadCare Plus Systems and to add these changes to the labeling for those devices. For example:

a. LeadCare II

- Your firm opened Engineering Change Order (ECO) #7060, dated 11/17/2016, to revise the LeadCare II labeling to include a four-hour incubation time. However, your firm documented that the change did not require validation/verification of the product or process and did not indicate whether an update to Risk Management documentation was required, despite the change being classified by your firm as a **(b)(4)** change,

which your ECO defines as “affects the design, production, or assessment of product form, fit, or function.”

• In ECO #7060, Form 123-05, “Regulatory Decision”, Rev 00, Page 2, your firm documented in the Decision Summary section that the change was classified as **(b)(4)**, which requires submission to FDA prior to implementation of the change and instructs to “Complete a 510(k) Notification and Technical File as required.” However, your firm did not follow this instruction in the procedure and instead noted on Form 123-05 that “this is a MedWatch (MDR) filing.”

b. LeadCare Ultra

• Your firm opened ECO #6968, dated 08/04/2015, to revise the LeadCare Ultra labeling to include, among other things, an instruction to allow mixture of patient blood samples and treatment reagent to stand for 24 hours prior to analysis. However, your firm documented that the change did not require validation/verification of the product or process and did not indicate whether an update to Risk Management was required, despite the change being classified as a **(b)(4)** change, which your ECO defines as “does significantly affect the form, fit, function, or regulatory status of the product” and that “may affect product performance.” Further, ECO #6968 also references Validation Report 157, but your firm’s management stated during the inspection that the referenced validation study was cancelled and that a different validation study was the correct validation study.

• In ECO #6968, Form 123-05, “Regulatory Decision”, Rev 00, your firm identified the change as **(b)(4)** although it was as classified **(b)(4)** on Form 123-04, Engineering Change Order Classification of Changes. In addition, on Form 123-05 in ECO #6968, your firm answered “Yes” to Question 5 of Section III B – Labelling Changes and “Yes” to Question 3 of Section III D – Materials Change For IVD. Based on those answers, Form 123-05 instructs that the regulatory decision for the change is “**(b)(4)**,” which states that the change requires submissions prior to implementation. However, **(b)(4)** is documented on the form instead of **(b)(4)**. **(b)(4)** requires only updated documentation/justification to be maintained rather than a new regulatory submission.

c. LeadCare Plus

• Your firm opened ECO #6944, dated 05/05/2015, to revise the LeadCare Plus labeling to include a 24-hour incubation time. However, your firm documented that the change did not require validation/verification of the product or process. Further, ECO #6944 also references Validation Report 157, but, as noted above, your firm’s management stated during the inspection that this validation study was cancelled.

• In ECO #6944, Form 123-04, Classification of Changes”, Rev 00, your firm classified the change as a **(b)(4)** change that “does not significantly affect the design, production, or assessment of form, fit, function, and regulatory status of the product.” However, your firm’s “Blood in Treatment Reagent Stability Study Part 1 – 090513 Report”, regarding a study conducted to assess the signal obtained on certain blood sample/treatment reagent mixtures, stored at room temperature over time using LeadCare Ultra sensors, states that a “change of instruction to include incubation time would require resubmitting data to FDA.”

We reviewed your firm's response and conclude that it is not adequate. We acknowledge that your firm provided updated ECOs 6944 and 6968 to include a reference to the report entitled "LeadCare Ultra/Plus Retrospective Summary Report for **(b)(4)** (Incubation Time)". Your response also states that you have initiated Corrective Action Plan, CAR-1223 and that the definitions related to the **(b)(4)** of changes identified in your ECO procedure, which relate to the potential impact of the change on design, production, or product form, fit or function, do not adequately identify changes that have the potential to affect a product's clearance, stability, or validation studies. Further, your response states that the Regulatory Decision checklist that supports ECOs does not adequately address all change elements that should be considered when determining the impact on existing 510(k)s and the need for premarket submissions. Your response also states that your firm will complete a **(b)(4)** and that comprehensive training, including training on change controls, will be provided by **(b)(4)**. Please keep our office updated on your ECO **(b)(4)** and provide supporting documentation for your firm's corrective actions.

6. Failure to establish procedures to control product that does not conform to specified requirements, pursuant to 21 CFR 820.90(a). For example, "Non-Conforming Material Procedure", SOP 113, Rev 2, defines "Use-As-Is" as **(b)(4)**." Your firm decided to "use-as-is" Controls with an initial average value assignment that would result in a range with a lower limit below the testing range for the LeadCare II after your firm changed the LeadCare II Lead Control Level 1 average value assignment for Lot # 1507N (Nonconforming Product Record NCP ID # 1175 opened 9/24/2015) and Lot # 1511N (Nonconforming Product Record NCP ID # 1193 opened 12/29/2015) without documenting that the Controls were verified to be acceptable for use. The lots identified in these nonconforming product records were later the subject of 71 Customer Complaints regarding customers unable to use their analyzers, due to the Controls being out-of-range.

We reviewed your firm's response and conclude that it is not adequate. Your response states that you have initiated Corrective Action Plan CAR-1231 and that a **(b)(4)**, as well as the forms and processes used by your material review board to evaluate instances of non-conformity. Further, your response states that your **(b)(4)** to assess the impact of these uses on affected products. However, you have not provided any supporting documentation in your response demonstrating that you have retrospectively evaluated Lots #1507N and #1511N, and related complaints, which were included in the above example. You also have not provided supporting documentation for your firm's other corrective actions.

Our inspection also revealed that your firm's LeadCare Ultra System is misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant violations include, but are not limited to, the following:

1. Failure to submit an MDR to FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets has malfunctioned and this device or a similar device that your firm markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example:

a. On January 12, 2017, your firm became aware of a customer complaint (Case # 00132411), in which a customer reported that the LeadCare Ultra System was providing low results in comparison to results obtained using another testing method. A February 13, 2017 comment in the file for Case #0132411 concludes that the customer's complaint is confirmed. FDA has not received an MDR for this event.

b. Your firm submitted MDR # 1218996-2015-00001, which FDA received on April 6, 2015. This MDR states that on August 13, 2014, your firm received complaints (Case #s 00110598 and 00110639, which indicated that two of your customers were getting higher results when repeating tests on the LeadCare Ultra System. In addition, MDR # 1218996-2015-00001 states that your firm received a complaint (Case # 00112168) on October 23, 2014, which indicated that another customer had observed differences between results obtained from the LeadCare Ultra System and those obtained from another blood lead analyzer. Your firm failed to submit an individual MDR within the required 30 calendar day timeframe for each MDR reportable event involving discrepancies in test results after testing using your firm's LeadCare Ultra System, of which your firm became aware through Complaint Case #s 00110639, 00110598, and 00112168.

We reviewed your firm's response dated July 21, 2017 and conclude that it is not adequate. Although your firm initiated a corrective action plan, CAR-1230, which is to include, among other things, a retrospective review to identify any past instances of MDR reportable events that were not reported to FDA, the Agency has not yet received individual MDRs for the MDR reportable events represented by Complaint Case #s 00112168, 00110639 and 00132411. Additionally, your firm did not provide supporting documentation for the corrective actions described in your response.

2. Failure to adequately develop, maintain and implement written MDR procedures, as required by 21 CFR 803.17.

a. Your firm's procedure, "Adverse Event Procedure, SOP 108, Rev 4, dated 3/29/2016," does not establish internal systems that provide for timely transmission of complete medical device reports, as required by 21 CFR 803.17(a)(3). Specifically, the following are not addressed:

- The procedure does not include a process for submitting MDRs electronically in accordance with 21 CFR 803.12(a) and 21 CFR 803.20. Information about the Final Rule for electronic Medical Device Reporting (eMDR), published in the Federal Register on February 14, 2014, and the eMDR set-up process can be found on the FDA website at: **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/default.htm (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR%E2%80%93ElectronicMedicalDeviceReporting/default.htm)**

- How your firm will submit all information reasonably known to it for each event. Specifically, which sections of the 3500A will need to be completed to include all information found in the firm's possession and any information that you can obtain by contacting a user facility, importer, or other initial reporter or by analysis, testing or other evaluation of the device.

b. In addition, the procedure does not describe how your firm will address documentation and record-keeping requirements, as required by 21 CFR 803.17(b), including requirements for systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

Our inspection also revealed that your firm's LeadCare Ultra System and Lead Care II System are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting those devices that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806 – Medical Devices; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following: