Inspections, Compliance, Enforcement, and Criminal Investigations

North American Medical Corporation 02-Mar-07

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Atlanta District Office
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Atlanta, GA 30309
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March 2, 2007

VIA FEDERAL EXPRESS

Carlos Becerra, President/CEO
North American Medical Corporation
1649 Sands Place, SE, Suite A&B
Marietta, Georgia 30067-8786

WARNING LETTER
(07-ATL-06)

Dear Mr. Becerra:

During an inspection of your firm located in Marietta, Georgia on September 19, 2006, through October 12, 2006, the investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Accu-Spina and the Da Vinci X10. 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 are intended to affect the structure or function of the body.

This inspection revealed that these devices 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 (CGMP) requirements of the Quality System (QS) regulation found at Title 21, **Code of Federal Regulations** (C.F.R.), Part 820. We received your unsigned response

dated November 9, 2006, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (copy enclosed) that was issued to Ms. Chello Grace, COO. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to document corrective and preventive action activities, including investigations of causes of nonconformities, the verification or validation of corrective actions, implementation of corrective and preventive actions, and dissemination of information about quality problems or nonconforming product to responsible parties, as required by 21 CFR 820.100(b). For example:

a. CAR #05-087 was created on 10/27/05 in regard to complaints received by the firm involving the decompression head malfunctions in the Accu-Spina device. The root cause of the decompression head malfunctions was not documented in the CAR #05-087. The following corrective actions were listed, however, no effectiveness verification was performed to determine if the corrective actions were implemented and that the actions were appropriate: design change and bearing alignment corrections, replaced for a better clutch, software change to 2.5, developing new criteria for training issues regarding discrepancies with patient angle positioning for treatment. In addition, the signature of the approving official for the corrective actions was not provided on CAR #05-087.

b. CAR #05-085 was created on 10/27/05 in regard to complaints received by the firm involving vibra heat malfunctions. The root cause in CAR #05-085 indicated that the malfunctions resulted from a control board design error. The corrective actions listed in CAR indicated that the vendors would be made aware of the malfunctions. However, no documentation was provided that indicated the vendors were contacted with regard to the corrective actions listed in the CAR. The firm did not provide documentation of that CAR effectiveness verification or validation was performed to determine if the corrective actions were appropriate. In addition, the signature of the approving official for the corrective actions was not provided on CAR #05-085. A Supplier Corrective Action Report (SCAR) was not issued as required by QSP 8.5-1 "Corrective and Preventive Action" dated 07/06/05.

Your firm's response dated 11/09/2006 is not adequate because you have not provided copies of the new CAPAs that were generated in response to the FDA-483 observation. You stated in your response that you have increased your staff and

assembled an internal audit team to perform quality system audits on a quarterly basis. Please provide the new CAPAs that were issued to replace the previous CARs as well as copy of the revised CAPA procedure that was issued in early 2006.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a). For example:

a. Complaints were not reviewed and evaluated according to QSP8.2-2 "Customer Complaints." Complaint information numbers 05-0583 through 05-0622 were assigned existing complaint numbers. The complaint information contained within the existing complaint numbers was removed from the complaint handling system and was filed separately.

b. Complaint #05-0573 was received on 09/30/05 which indicated that patients were complaining that the vibra heat component was getting too hot and causing burns. The complaint referenced CAR #05-085 under the investigation section on the complaint form. However, CAR #05-085 did not document the results of the investigation into complaint #05-0573.

Your firm's response dated 11/09/2006 is not adequate. You stated in your response that you have updated QSP 8.2-2 "Customer Complaints" and revised the customer complaint handling software to allow for trend analysis based on malfunction code. You have not provided-a copy of QSP 8.2-2 "Customer Complaints" for FDA review. The validation of the software used to perform the trend analysis has not been provided to support your firm's claim that the software can be used effectively to prevent the firm from overlooking complaints. In addition, you have not addressed how you corrected the observations that were made during the FDA inspection. Specifically, you have not provided the documentation of the investigation into the complaints that were identified in the FDA-483. Please provide for FDA review the documentation of investigation into the complaints, revised procedure QSP8.2-2 "Customer Complaints," and the software validation that was performed on the complaint handling software used for trend analysis.

3. Failure to document the justification for use of the nonconforming product and the signature of the individual(s) authorizing the use, as required by 21 CFR820.90(b)(1). For example, documentation for Nonconformance IDs #05-176 and #05-186 was not provided during the current inspection. Nonconformance ID #05-176 involved the repair of a set of weak vibrating motors from the **[redacted]** and Nonconformance ID #05-186 involved the replacement of the defective Vibra-heat cushions received from **[redacted]** Ms. Washington, FDA Manager for the firm, could not locate the records for Nonconformance IDs #05-

176 and #05-186.

Your firm's response dated 11/09/2006 is not adequate. You stated that you have revised procedure QSP 8.3-1 "Control of Non-Conformance" and QSP 8.2-5 "Material Review Board" to ensure that future nonconformances are properly documented. You did not provide these procedures for FDA review. In addition, you indicated that you have scheduled an audit of all historical data. You have not provided any additional information concerning this audit. Please provide copies of your revised procedures QSP 8.3-1 and QSP 8.2-5, documentation of the~ two instances of nonconforming product Nonconformance IDs #05-176 and #05-186, that were not provided at the time of the inspection.

4. Failure to perform testing on the design using production units under actual or simulated use conditions, as required by 21 CFR:820.30(g). For example, during the inspection of the facility, the investigator asked Ms. Washington, FDA Manager, about the design validation for the Da Vinci X10. She stated that the firm only conducted software validation for the device. In addition, the design history file for the Spina Systems-Da Vinci did not include a completed design validation as required by QSP7.3-4 "Design Verification Process."

Your firm's response dated 11/09/2006 is not adequate. You stated that you have opened a CAPA in response to this observation as well as updated the Design History File to include all of the required information concerning the design validation for the Da Vinci X10. However, you have not provided this information for FDA review. Please provide your documentation that shows that your firm has performed design validation using production units of the Da Vinci X10 under actual or simulated use conditions.

5. Failure to document the results of the design verification, the method, date and individuals performing the design verification in the DHF, as required by 21 CFR 820.30(f). For example, the design history file for the Spina Systems-Da Vinci X10 did not include a complete Design Verification Form as required by QSP 7.3-4 "Design Verification Process." The design history file did not contain documentation of the verification activities that demonstrate that the design inputs meet the design outputs.

Your firm's response dated 11/09/2006 is not adequate. You stated that you have opened a CAPA in response to this observation as well as updated your Design History File to include all of the required information concerning the design verification for the Da Vinci X10. However, you have not provided this information for FDA review. Please provide documentation that states that your firm has performed design verification and documented it according to QSP7.3-4 "Design Verification Process."

6. Failure to document design output in terms that allow an adequate evaluation of conformance to design input requirements, as required by 21 CFR 820.30(d). For

example, the design history file for the Spina Systems - Da Vinci X10 did not include a completed design output form as required by QSP 7.3-4 "Design Verification Process." The design history file for the device contained a Bill of Materials (BOM) document that lists the parts of the device; however, the device history file does not include documentation of the design outputs meeting the predetermined acceptance criteria.

Your firm's response dated 11/09/2006 is not adequate. You stated that you opened a CAPA in response to this observation as well as updated the Design History File to include all of the required information concerning the design outputs for the Da Vinci X10. However, you did not provide this information for FDA review. Please provide documentation that states that you have evaluated the design outputs for the Da Vinci X10 to ensure that they meet their predetermined acceptance criteria and documented it according to QSP7.3-4 "Design Verification Process."

7. Failure to establish a design and development plan, as required by 21 CFR 820.30(b). For example, the design history file for the Spina Systems - Da Vinci did not include a design and development plan as required by the firm's procedure QSP 7.3-4 "Design Verification Process." In addition, no documentation of a design and development plan for the Da Vinci X10 was provided during the inspection.

Your firm's response dated 11/09/2006 is not adequate. You stated that you opened a CAPA in response to this observation as well as updated the Design History File to include all of the required information concerning the design and development plan for the Da Vinci X10. However, you did not provide this information for FDA review. Please provide your design and development plan for the Da Vinci X10 to the FDA for review.

8. Failure to document device identifications and control numbers in the device history record, as required by 21 CFR 820.184(f). For example, the device history records for the Accu-Spina Cervical devices did not contain the control number for the assembled cervical control box which was used as a component within each device. The specific design history records found to be without control numbers were CC2051, CC2057, CC2040, 21-0228-444, 21-031-245, and21-230-446.

Your firm's response dated 11/09/2006 is not adequate. You-did not provide copies of the assembly forms that will be placed into the respective devices design history records for FDA review. In addition, you did not address how you will prevent this lack of documentation from occurring in the future. You stated that the component serial numbers for the component parts were recorded in the **[redacted]** [undefined acronym] system. The assembly forms have been revised to capture information about the assembly of finished devices and list the serial numbers for critical components. You indicated that your firm's personnel are filing the assembly forms for each component in the design history record. Please provide a revised version of the procedure for maintaining design history records

or identify how you will ensure that the appropriate information will be documented in the design history record.

9. Failure to document acceptance test results-of in-process product, as required by 21 CFR 820.80(c). For example, the device history" record for Accu-Spina Cervical device CC2051 did not contain the correct lumbar calibration test results. Serial number CC2051 was manufactured in July and August 2003; however, the lumbar calibration test for the unit was dated January 2003.

Your firm's response dated 11/09/2006 is not adequate. You have not provided copies of Forms QS-100 and QS-2000, the checklists that will be used to ensure that all appropriate documents are found the DHR. In addition, you have not addressed how you will prevent this lack of documentation from occurring in the future.

You stated that you have created checklists to ensure that the content of the DHR for each device is accurate. In addition, you stated that the DHRs are reviewed and affirmed by the North American Medical quality department prior to the shipment of the device. Please provide a revised version of the procedure for maintaining design history records or identify how you will ensure that the appropriate information will be documented in the design history record.

Lack of Medical Device Reporting

Our inspection also revealed that your devices 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 the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 C.F.R. Part 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

> Failure to conduct an investigation of each event and evaluate the cause of the event, as required by 21 CFR803.50(b)(3). For example, complaint #05-0573 was received on 09/30/05, which indicated that patients were reporting that the Vibra heat component on an Accu Spina device (serial number M-21-0110-332) was too hot and it burns. The complaint form does not identify the type of burn that the patient experienced or any additional information concerning the incident.
>
> Your firm's response dated 11/09/2006 is not adequate. You stated that the amount of heat supplied to the patient by the Accu Spina Vibra heat component only caused the patient some discomfort and was not hot enough to cause or contribute to a death or serious injury based on the firm's investigations. This investigation was not included as part of the complaint form. In addition, you note that the firm decided to discontinue the use of the **[redacted]** heating pad and replace them

with the **[redacted]**

You have not provided documentation of your investigations into this complaint. Please provide documentation of the investigation to the FDA for further review. In addition, please identify how your firm will prevent the lack of documentation of the investigation and submit your procedures for MDR reporting.

Lack of Premarket Submission

The Act requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

A review of our records has determined that you have not obtained marketing clearance or approval for your firm's Da Vinci X10 with new software control and the Accu-Spina containing the **[redacted]** software,and the vibrator/heater accessory, which is a violation of the law. Our records indicate that your firm's 510 (k), K92103, was cleared for the Da Vinci X10 without software. Our records also indicate that your firm's 510(k), K033231, was cleared for the Accu-Spina without the **[redacted]** software and without the vibrator/heater accessory. The FDA has determined that these are significant changes which require the submission of a new premarket notification [510(k) submission] under 21 CFR 807.81(a)(3). This determination is based on the fact that these changes could significantly affect the safety or effectiveness of the device and that there was a major change or modification in the intended use of the device.

Because of this change, the Da Vinci X10 and Accu-Spina are adulterated within the meaning of section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), for failure to obtain FDA premarket approval, and misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not submit a section 510(k) premarket notification that shows your modified devices are substantially equivalent to another device that is legally marketed. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act is deemed to be satisfied, under 21 CFR 807.81(b), when a premarket approval application (PMA) is pending before the agency. The kind of information you need to submit in order to obtain this clearance is available through the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate this information and decide whether your product maybe legally marketed.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include; but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are

advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violation(s), from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your response to Serene N. Ackall, Compliance Officer at 60 Eighth Street, NE, Atlanta, Georgia 30309. If you have any questions about the content of this letter please contact Serene N. Ackall at 404-253-1296.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483, issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

/S/

Mary H. Woleske, Director
Atlanta District

Enclosure

Warning Letter Response

- North American Medical Corporation Response Letter