U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Gulf Medical Fiberoptics, Inc. 7/27/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-11-34

July 27, 2011

Patrick R. Bennetts
President
Gulf Medical Fiberoptics, Inc.
448 Commerce Blvd
Oldsmar, FL 34677

Dear Mr. Bennetts:

During an inspection of your firm located in Oldsmar, Florida on April 27, 2011 through May 3, 2011, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures endoscopic fiber optic cables and Visualux™ surgical headlights. 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 (CFR), Part 820.

We received a response from Mr. Craig S. Vogeley, Vice President Operations, dated May 23, 2011, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to you. 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 establish and maintain adequate procedures for implementing corrective and preventive action that include the requirements for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, you did not implement Section 5.6 of your Complaint/Corrective Action procedure, P-852, Rev C, which requires proposed corrective action to be verified or validated prior to implementation. You changed the dimensional specifications for one of the connectors, Drawing #1000043, used as a component of your Endoscopic Cable device, which was proposed under Corrective Action #32; however, your records do not demonstrate this proposed specification change was verified or validated prior to implementation.

We reviewed your response and conclude that it is not adequate because your firm did not conduct or document the verification for corrective action # 32 that was specific to dimension changes to the **(b)(4)** connector. Your firm has been aware of this issue since the initiation of this corrective action on July 19, 2010. Your firm's previous response dated October 5, 2010, to the FDA 483 issued to your firm on September 17, 2010, stated that all of the required information would be added to this corrective action no later than October 29, 2010.

2. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test that the process is validated with a high degree of assurance and approved according to established procedures, as required by 21 CFR 820.75(a). For example:

A. Your validation study for your process to manufacture optical fibers, conducted under Fiber Optic Drawing Tower Validation Master Plan, F-750-009, Rev A, did not include complete analysis of the Furnace Temperature process variable in order to demonstrate the effect it may have on finished product quality. The OQ portion of the protocol did not analyze temperatures above 1800°F, and records covering the PQ portion of the protocol did not demonstrate inclusion of operating temperatures above 1804°F, although your listed 1810 - 1775°F as the acceptable range for the Furnace Temperature processing variable.

B. Your records covering validation of your process to manufacture optical fibers, conducted under Fiber Optic Drawing Tower Validation Master Plan, F-750-009, Rev A, do not include identification of the instruments used to measure the Furnace Temperature and Take-Up Wheel Speed process variables and, thus, do not demonstrate these measuring devices were calibrated at the time of their use in the study.

C. You have not validated the cleaning process for your Visualux brand surgical headlight device, listed in the Instructions For Use that you distribute with the device, in order to demonstrate the cleaning process is consistently effective.

The adequacy of your response cannot be determined at this time. Your firm did not include documentation or evidence of the corrections and corrective actions specific to the cleaning validation for the surgical headlights. However, your firm provided adequate validation documentation for the furnace temperature and calibration data specific to the tachometer and thermometer. Additionally, this was a repeated deficiency from your previous FDA inspection of September 9 - 17, 2010.

3. Failure to establish and maintain adequate procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate, as required by 21 CFR 820.30(g). For example, you did not re-evaluate the Failure Modes and Effects Analysis (FMEA) for the Endoscopic Cable device as part of Corrective Action #32, and your record of the previous FMEA for this device listed a maximum likelihood for detecting a failure mode resulting from incorrect dimensions being selected during the design process.

The adequacy of your response cannot be determined at this time. Your firm did not include documentation or evidence of the corrections, corrective actions, or evidence of implementation specific to the updated Failure Mode and Effects Analysis for the Endoscopic Cable and Corrective Action procedure P-852 to ensure corrective action findings require a re-evaluation of the failure mode and risk. Additionally, this was a repeated deficiency from your previous FDA inspection of September 9 - 17, 2010.

4. Failure to document acceptance activities, as required by 21 CFR 820.80(e). For example, you do not document the results of final acceptance testing covering connector fit testing for your Endoscopic Cable device.

We reviewed your response and conclude that it is not adequate. Your firm's current F-750-010 Final Inspection form, Revision D, did not have a designated area to document the end tip final polish length. Additionally, your firm did not provide evidence of implementation for the Work Instruction WI-750-028 Fiber Optic Cable In Process and Final Inspection. Additionally, this was a repeated deficiency from your previous FDA inspection of September 9 - 17, 2010.

5. Failure to establish and maintain adequate requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). For example:

A. Your Supplier Evaluation Form, F-740-002-A, referenced for use under Section 4.2.4 of your Purchasing procedure, P-740, Rev D, does not ensure vendors are evaluated based on criteria demonstrating their ability to meet quality requirements.

B. You did not implement Section 4.2 of your Purchasing procedure, P-740, Rev D, covering procedures to evaluate and select the contract servicer **(b)(4)** and laboratory **(b)(4)** used to execute the validation study covering the cleaning process listed in the Instructions for Use for your Visualux Fiber Optic Headlight.

We reviewed your response and conclude that it is not adequate. Your firm did not provide any evidence that they qualified their contract servicer **(b)(4).** Additionally, your firm did not provide evidence of implementation for the revised Purchasing Procedure P-740 or the proposed draft version for the Supplier Evaluation Form F-740-002.

6. Failure to maintain adequate device history records (DHRs). Each manufacturer shall establish and maintain procedures to ensure that DHRs for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of 21 CFR 820. The DHR shall include, or refer to the location of, the primary identification label and labeling used for each production unit, as required by 21 CFR 820.184(e). For example, the DHRs covering production of your Endoscopic Cable devices for March 11 - 15, 2011, and April 8 - 26, 2011, did not include or reference all labels applied to the devices such as:

A. The stick-on label applied to the device identifying the responsible firm information was not included or referenced in 7 of 55 records reviewed.

B. None of the records reviewed included or referenced the sterilization label.

The adequacy of your response cannot be determined at this time. Your firm stated they will open a corrective action to determine why the DHRs were missing the responsible firm's label. Additionally, your firm did not include documentation or evidence of implementation specific to the revised F-750-010 Final Cable Inspection Form and Work Instruction WI-750-028.

7. Failure to maintain adequate device master records (DMR's), as required by 21 CFR 820.181. For example, the Device Master Record for the Endoscopic Cable device did not include or refer to the location of the following manufacturing and quality acceptance procedures utilized by your production employees to manufacture your Endoscopic Cable device:

A. Fiber Bundle Acceptance, WI-750-014

B. Low Temperature Epoxy Application, WI-750-012

C. High Temperature Epoxy Application, WI-750-001-013

The adequacy of your response cannot be determined at this time. Your firm did not include documentation or evidence of the corrections, corrective actions, or evidence of implementation specific to the proposed Endoscopic Cable device master record revision.

8. Failure to establish and maintain adequate procedures to control all documents, as required by 21 CFR 820.40. For example:

A. Unapproved, electronic quality system documents are available for use by your department managers.

B. Section 5.3.1 of your Document Control procedure, P-423, Rev D, requires only the hard-copy signature of your Quality System Management Representative to demonstrate approval of a document, although the procedure also requires your department managers to approve documents used in their area of responsibility.

C. You have not implemented Section 5.3.1(b) of your Document Control procedure which requires you maintain a Master Document List, F-423-001, listing all approved quality documents.

Your response to this observation appears to be adequate. However, this was a repeated deficiency from your previous FDA inspection of September 9 - 17, 2010.

9. Failure to establish and maintain adequate procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s), as required by 21 CFR 820.30 (c). For example, your Design Plan for Endoscopic Cables, F-730-001-A, dated March 2, 2002, did not list all appropriate design input requirements, including:

A. Light transmission performance requirements.

B. Dimensional requirements for optical fiber components.

C. Dimensional requirements to ensure compatibility with standard connectors.

D. Capability to withstand/prevent physical stress.

Your response to this observation appears to be adequate.

10. Failure to establish adequate procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct

responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited, as required by 21 CFR 820.22. For example:

A. You did not implement Section 5.2 of your Internal Audits procedure, P-822, Rev B, which requires the initiation of the internal audit based on the master schedule, in that you began internal audit procedures on June 22, 2010, although the Internal Audit Plan, F-822-001, for this audit was not created until June 23, 2010. Further, the record for this audit plan was not approved by the Quality System Management Representative as required under Section 5.1 of the procedure.

B. Your Internal Audits procedure, P-822, Rev B, does not require a report of the results of each quality audit be reviewed by the management responsible for the matters audited, and your records do not demonstrate such reviews have taken place.

Your response to this observation appears to be adequate.

A follow up inspection will be required to assure that corrections and/or corrective actions are adequate.

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 the Food and Drug Administration 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 violations 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 business days from the date you receive this letter of the specific steps you have taken to correct the noted violations, as well as an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If your planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of these activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your response should be comprehensive and address all violations included in this WL.

Your response should be sent to Andrea H. Norwood, Compliance Officer at 555 Winderley Place, Suite 200, Maitland, FL 32751. Refer to the Unique **Identification Number (CMS case # 195372)** when replying. If you have any questions about the content of this letter please contact: Ms. Norwood at (407) 475-4724 or by facsimile (407) 475-4768.

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 violation(s) noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management 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/
Edwin Ramos
Acting Director, Florida District

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