# Inspections, Compliance, Enforcement, and Criminal Investigations

# Biomed Devices Corporation (AKA: Medlens Innovations, Inc.)

hhsbluebird **Department of Health and Human Services**

Public Health Service
Food and Drug Administration
Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

FEI: 1000123221
CMS#46158

**WARNING LETTER**

**February 2, 2009**

**CERTIFIED MAIL**
**RETURNED RECEIPT REQUESTED**

Mr. Robert O. Breece, OD
President & CEO
Biomed Devices Corporation
1325 Progress Road
Front Royal, Virginia 22630-6425

Dear Mr. Breece:

During an inspection of your firm located in Front Royal, VA, on October 23 through 27, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures daily wear soft and

rigid contact lenses. 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 any function of the body.

This inspection revealed that your 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 a response from you dated December 22, 2008, 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 the noted violations. These violations include, but are not limited to, the following:

**Quality System Requirements**

1. Failure of management to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization **[21 C.F.R. § 820.20]**. Specifically, you have not ensured that a quality system is maintained at all levels of the organization and in the areas of management responsibility, corrective and preventative actions, and production and process controls.

Your December 22, 2008 response to this observation was that "the initial Quality System procedures are being documented and implemented" and will be in place by December 31, 2008, including training of the appropriate individuals on the implementation of the procedures and "necessary process controls." Your response is inadequate, however, because you did not provide any documentation of the "Quality System procedures" or "process controls" to be implemented.

2. Failure to conduct quality audits at sufficient intervals, as prescribed by internal procedures, to verify that the quality system is effective in fulfilling your quality system objectives **[21 C.F.R. 820.22]**. Specifically, your firm does not follow its SOP **(b)(4) -** "Periodic Review of Records," and SOP **(b)(4)** "Internal Audit Report Format." SOP **(b)(4)** requires monthly Quality Assurance (QA) reviews of changes and additions to the device master record, raw materials logs, equipment and facilities maintenance logs, returned product and complaint

logs, and lens fabrication logs. The review is to be documented according to the format outlined in SOP **(b)(4)**, and is to include deviations from SOPs or deficiencies, corrective actions taken, signature and date of the person performing the audit, and review by the chief executive officer or director of operations. There is no record that these monthly reviews have been performed.

**Production and Process Controls**

3. Failure to conduct process controls in accordance with documented instructions and standard operating procedures **[21 C.F.R 820.70(a)(1)]**. Specifically, your firm does not consistently follow its SOP **(b)(4)** - "Biological Indicator Validation," and SOP **(b)(4)** - "Product Sterilization Release," for the sterilization of soft contact lenses, and does not accurately and consistently complete the required documentation and release forms. SOP **(b)(4)** requires that biological indicators for each autoclaved batch of soft lenses must be allowed to incubate for **(b)(4)** hours. SOP **(b)(4)** requires the lab supervisor to verify the operating time and temperature of the autoclave for each batch, verify that the biological indicators have incubated for a minimum of hours at the required temperature, and record the results of the verifications on the "Product Sterilization Report." **(b)(4).** At least 20 of the approximately 100 sterilization records entitled "Wet Lens Processing Log" that were reviewed during the inspection and dated January 2007 through October 2008, were incomplete in that quarantine dates, release dates, signatures, and/or documentation of "growth" or "no growth" for the "BioSign Indicators" were missing. The devices that were processed according to these logs were released and shipped to customers with no documentation that they were sterilized.

4. Failure to implement process control procedures that describe any process controls necessary to ensure conformance to specifications [21 C.F.R. 820.70 (a)]. Specifically, your firm does not follow its SOP **(b)(4)** - "In-Process Quality Control Audits," which requires that QA personnel perform daily audits of at least **(b)(4)** base curves, **(b)(4)** front curves, **(b)(4)** completed dry lenses, **(b)(4)** hydrated lenses, and **(b)(4)** labeled lenses (per **(b)(4)** manufactured). Should anyone sample fail in any production, this SOP provides that the QA personnel will audit **(b)(4)** of the lenses until **(b)(4)** lenses passed by the operator are also passed by the QA person. This SOP also states that the QA personnel will **(b)(4)**

5. Failure to document equipment calibration and maintenance **[21 C.F.R. 820.72(a)]**. Specifically, your firm's SOP **(b)(4)** - "Daily Calibration Procedures: **(b)(4)** requires **(b)(4)** calibration of the machine before use, and states that the calibration results must be recorded on the **(b)(4).** This machine

is used to cut and shape all of the contact lenses manufactured by your firm. Your firm verbally stated that the **(b)(4)** is calibrated **(b)(4)** but there is no record of this activity. Also, your firm does not have a written procedure or maintenance schedule for routine and unscheduled maintenance the **(b)(4)** or other key pieces of equipment used in the manufacture of contact lenses, including the **(b)(4)** (used to verify the lens base curve and front curve) and the **(b)(4)** (used to verify the lens power). Your firm was also cited for this violation during a July 2003 inspection at your firm.

**Acceptance Activities**

6. Failure to implement procedures for finished device acceptance to ensure that each production run, lot, or batch meets acceptable criteria **[21 C.F.R. 820.80 (d)]**. Specifically, your firm does not follow its SOP **(b)(4)** - "Quality Assurance of Final Packaging of Product," which requires that, before product can be packaged for shipment, the QA clerk must check the package labels against the work order and verify that the label is correct. This SOP further provides that, after verification, the QA clerk must place his/her initials next to the round barcode labels on the work order. Of the 255 device records reviewed during the inspection, all were missing the QA clerk's initials to document verification of the work order and label before shipment.

**Records**

7. Failure to establish, maintain, and implement procedures for reviewing and evaluating complaints **[21 C.F.R. 820.198(a)]**. Your firm's SOP **(b)(4)** - "Return/Complaint File," requires that product returns or complaints must be recorded in the "Return/Complaint Log," and that the log is to be reviewed daily by a supervisor who must investigate identified problem areas and provide recommendations for corrections to the General Manager. This SOP further provides that, at the end of each week, the supervisor must submit a summary report to management containing a tally of complaints and reasons for product returns. Your firm does not follow this SOP, as there is no documentation that daily and weekly reviews of the Return/Complaint Logs have been performed. Your firm has no written procedure describing how to evaluate complaints to determine if an investigation is necessary or describing implementation of corrective and preventive actions that may be required.

**Nonconforming Product**

8. Failure to establish and implement procedures that set forth the review and disposition process for nonconforming product **[21 C.F.R. 820.90(b)(1)]**. Specifically, your firm's SOP **(b)(4)** - "Non Conforming Lens," requires that any lens rejected in process will be recorded on the "Non Conforming Lens Log." However, you have no procedure to describe the review of these logs or what actions must be taken to investigate the causes of the non-conformances and to prevent the reoccurrence of any identified problems. Your firm was also cited for this violation during a July 2003 inspection at your firm.

Your December 22, 2008 response addressed Observations 2-8 above by stating that re-writing the procedures and re-training of personnel on the procedures and necessary process controls will address the deficiencies, and will be completed by December 31, 2008. This response is inadequate because you provided no documentation of the procedures and process controls to be revised or the training plan to be implemented, nor did you explain how revising the procedures will correct the deficiencies. You also did not address whether the deficiencies identified during the inspection affected the quality and safety of the devices distributed prior to the corrective actions.

Your response also noted that you hired an outside QSR consultant, who made the following recommendations:

a.) Hire a person whose primary job is to direct and oversee regulatory compliance for the firm, including performing audits and overseeing adherence to the QS procedures. You stated that such a person was hired "three weeks ago." However, you did not provide any documentation about this expert, including his/her name or qualifications, or the reporting structure for the person within the firm.
b.) Purchase software specific to contact lens firms, which has quality system modules. You stated that you had purchased the software and planned to have it installed by January 2009, with implementation and validation within 5 to 6 months. However, you did not provide any documentation regarding the software system, the validation plan, or your firm's plan to train personnel on the use of the system.
c.) Rewrite and reorganize the firm's SOPs "to reflect the procedures that [you] have in place." You stated that you and the"newly hired regulatory compliance staff member will oversee this task. However, you did not provide any documentation regarding the planned SOP changes.

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 violations, or similar violations, 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.

Your response should be sent to: Randy F. Pack, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, MD 21217. If you have any questions about the content of this letter, please contact Mr. Pack at (410) 779-5417.

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 Inspection 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 yours,

/S/
Evelyn Bonnin
Baltimore District Director