U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

ASI Medical, Inc. 4/20/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Southwest Region
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April 20, 2011

WARNING LETTER

Mr. John W. McPeek
President
ASI Medical, Inc.
14550 E. Easter Ave., Suite 700
Englewood, CO 80112

VIA UPS

Ref # DEN-11-10 WL

Dear Mr. McPeek:

During an inspection of your firm located at 14550 E. Easter Avenue, Centennial, Colorado, on November 29, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures dental operative units. 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. You can find these regulations on the FDA website at www.fda.gov [1]

Significant deviations include, but are not limited to, the following:

1. You have failed to follow your firm's QS Standard Operating System Procedures (SOP) in the following required areas:

   • You have not maintained complaint files, documented complaint investigations, or Medical Device Reporting (MDR) evaluations, as required by your **(b)(4)**, Customer Service Contact/Complaint Handling, **(b)(4)**, (21 CFR 820.198). A limited review of your complaint log revealed five complaints that had not been fully documented or evaluated.

   • You have not followed your procedure to control product that does not conform to specified requirements, SOP **(b)(4)**, Nonconforming Items & Corrective Action, **(b)(4)**, (21 CFR 820.90(a)). No Quality Control Exception Reports have been created as of the date of this inspection, although two defective units were noted in the production area.

   • You have not followed your SOP **(b)(4)**, Corrective Action and Follow-Up, **(b)(4)**, (21 CFR 820.100(a)(1)). Although two corrective actions were noted during the inspection, to date, you have not prepared any Corrective Action Request forms which are required to initiate corrective actions.

   • You have not followed your SOP **(b)(4)**, Final QC & Finished Product, **(b)(4)(b)(4)**, that requires the device history record include a test certificate for **(b)(4)(b)(4)**," (21 CFR 8020.80(d)). Specifically, it was noted that your firm has not conducted the **(b)(4)** testing since December 2008.

   • You have not followed your SOP **(b)(4)**, Receiving, Inspection & Stocking of Parts & Materials, **(b)(4)** which states that incoming shipments will be inspected for conformance to specifications and reported on the Receiving and Inspection Report, (21 CFR 820.80 (b)). Specifically, your firm does not document the acceptance of incoming products.