Inspections, Compliance, Enforcement, and Criminal Investigations

American· Optisurgical Inc. 6/14/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

June 14, 2012

WL#25-12

Mr. Herbert Cameron, III
President/Chief Operating Officer
American Optisurgical Inc.
26902 Vista Terrace
Lake Forest, California, 92630-8123

Dear Mr. Cameron:

During an inspection of your firm located in Lake Forest, California, conducted from January 30, 2012 through February 23, 2012, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures the TX1 Tissue Removal System. 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 responses dated March 7, 2012 and May 29, 2012, concerning our investigators' observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you at the conclusion of the inspection. We address these responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1) Failure to validate the design under actual or simulated use conditions, as required by 21 CFR 820.30(g).

For example, the Process Validation Report for the TX1 Tissue Removal Console, dated August 11, 2011 did not reference that testing was conducted in actual or simulated conditions for which the devices will used. Additionally, there was no documentation that the devices used for design validation were subjected to your required 24 hour burn in process

prior to installation of the production software. Your responses, dated March 7, 2012 and May 29, 2012 are inadequate. You have not demonstrated that process validation for the TX1 Tissue Removal System has been performed under actual or simulated use conditions.

2) Failure to adequately document design inputs, as required by 21 CFR 820.30(c).

For example, design inputs for the TX1 Product Design Specification procedure were not reviewed and approved by the Project Manager of the TX-1 Design Project plan, as required by your firm's Design Control procedures, QOP-73-01, Rev. C. A change in the original design input for pressurized irrigation from **(b)(4)** nominal operating pressure to **(b)(4)** nominal operating pressure was not referenced in Design Review Minutes or in your Product Design Specifications. Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. You have not demonstrated that design inputs have been adequately documented.

3) Failure to adequately document design outputs, as required by 21 CFR 820.30 (d).

For example, design output requirements were not documented, reviewed and approved according to defined acceptance criteria before commercial release of this device. The Process Validation Report for the TX1 Tissue Removal Console, dated August 11, 2011 does not reference a protocol with defined acceptance criteria to demonstrate conformance to design input requirements. Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. You have not demonstrated that design output requirements have been met.

4) Failure to document process validation activities, as required by 21 CFR 820.75 (a).

For example, you have not documented that the process of manufacturing **(b)(4)** has been validated to assure these components meet your specifications. Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. You have not demonstrated that this process has been validated to meet predetermined specifications.

5) Failure to validate software used as part of production for its intended use according to an established protocol, as required by 21 CFR 820.70(i). For example, your firm has not validated:

- The software that operates the **(b)(4)** used to fabricate and manufacture **(b)(4)** for the TX1 Tissue Removal System.
- The burn in software used to test the TX1 Tissue Removal Console referenced in your Process Validation Report, dated August 11, 2011.

Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. You have not demonstrated that the above referenced software has been validated for its intended use.

6) Failure to adequately establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, Your Customer Complaints Procedure, QOP-85-03, Rev. B does not specify that the actual date the complaint was received, dates of the investigation and the results of the investigation needs to be documented. Our investigators' review of your complaint files revealed several deficiencies in complaint handling:

- Complaint files lacked contact information for the customer.
- There was no indication that there was any follow up with complainants.
- There was no determination whether the device was used during a medical procedure and if the complaint should be evaluated to determine if an adverse event should be reported to FDA.
- Your customer complaint reports and return goods authorizations do not indicate how a complaint was received (e.g. telephone, email, backdoor); therefore there is no mechanism in place to ensure all verbal complaints are captured.
- If a formal investigation was conducted and if not, the reason why no investigation was made.
- Whether the complaint led to a Corrective action for complaint records **(b)(4)** .

Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. Your promised

corrective actions referencing the updating of your complaint handling procedures have not yet been implemented.

7) Failure to adequately establish procedures for corrective and preventive action; as required by 21 CFR 820.100(a). For example, your firm's CAPA procedures, QOP-85-04, Corrective and Preventive Action do not require written documentation when proposing a Corrective Action Request, therefore limiting the ability to determine recurrence of nonconforming product or quality problems. Your firm has not defined what constitutes a sufficiently serious or recurring nonconformity'' in either your Corrective and Preventive Action procedures or your Supplier Evaluation and Monitoring procedure, (QOP 74-01) to define the criteria to initiate a Corrective Action Request. Additionally, your Control of Non-Conforming Product procedures (QOP-83-01) allow your form to close out non-conforming product reports if a disposition decision is made to "scrap" or accept product "as is" without further evaluation to determine if a corrective or preventive action is appropriate. Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. Your promised Corrective actions have not yet been implemented.

8) Failure to adequately establish document control procedures, as required by 21 CFR 820.40. For example, your firm's document control procedures, QOP-42-01) Control of Documents, Rev. D do not address how to control or identify **(b)(4)** used to download the software in finished devices. These. procedures do not have signature requirements that demonstrate documents, such as device history record documents· and design drawings have been approved. The documents are dated, and include the name of the individual approving the documents, but lack a signature. The software used to store the procedures, records and drawings do not have an electronic signature capability. Your firm's controlled documents do not reference historical changes made to them. As an example, "Red Line" changes to drawings referencing component assemblies and designs used for the Tenex TX1 Tissue removal System did ·not have the date and initials or signature of the individuals conducting the "Red Line" changes to these documents. Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. Your promised corrective actions have not yet been implemented.

9) Failure to establish procedures for design transfer, as required by 820.30(h). For example, your design control procedures, Design Control QOP-73-01 Rev. C do not indicate how the validated design is to be correctly transferred into production specifications. This procedure states "engineering is responsible for translating the device design into manufacturing specifications", but provides no requirements to demonstrate the drawings have been released to manufacturing. Your responses, dated March 7, 2012 and May 29, 2012 were inadequate. You have not demonstrated how the design of the Tenex TX1 Tissue removal System was transferred to manufacturing.

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 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 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 fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Finally, your response should be sent to: Mr. Blake Bevill, Director, Compliance Branch, Food and

Drug Administration, 19701 Fairchild, Irvine, CA 92612-2506. If you have any questions about the content of this letter please contact: Dr. William Vitale at 949-608-2919.

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 (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/

Alonza E. Cruse, Director
Los Angeles District

Cc: Ms. Ingeborg Small, Chief
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