Inspections, Compliance, Enforcement, and Criminal Investigations

Troy Innovative Instruments, Inc. 01-Nov-07

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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November 1, 2007

WARNING LETTER
CIN-08-34399-03

VIA FEDERAL EXPRESS

Thomas P. Cseplo
President/CEO
Troy Innovative Instruments, Inc.
15111 White Road
Middlefield, OH 44062-9216

Dear Mr. Cseplo:

During an inspection of your firm located in Middlefield, Ohio on September 6 through 27, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures various tools and impl antable orthopedic, and neurological devices, including trocars, lumbar bone screws, rods, nuts, plates and skull pins. 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.), Pa rt 820. These violations include, but are not limited to, the following:

1) Failure to validate manufacturing processes and approve according to established procedures, where the results cannot be fully verified by subsequent inspections and tests. [21 C.F.R. 820.75(a)] Specifically:

- The ultrasonic cleaning process has not been validated.

- The electropolishing process has not been validated.

- Computer Numerical Control (CNC) Machine #C-4 had out of specification results during operational qualification conducted during validation. These out of specification results were not investigated or addressed in the validation report.

- The passivation process validation was not performed on a full load. Additionally, there was no evaluation to determine the most difficult device to passivate.

- The heat treating process validation was not performed on a full load. Additionally, there was no evaluation to determine the most difficult device to heat treat.

2) Failure to include in your device history records complete acceptance records that demonstrate the device is manufactured in accordance with the device master record. [21 C.F.R. 820.184(d)]

Specifically, all seventeen of the device history records reviewed by the FDA investigator were incomplete. For example, quantities of devices were incorrect, passivation and sonic cleaning times were not recorded, out of specification results were not addressed, and final inspections were not documented.

3) Failure to analyze all sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. [21 C.F.R. 820.100(a)(1)] Specifically:

- The reasons the devices are being scrapped and the types of nonconformances being found are not being documented.

- The types of device nonconformances and the scrap rate are not being trended.

4) Failure to ensure that the corrective and preventive actions are effective. [21 C.F.R. 820.100(a)(4)]

Specifically, none of the 19 corrective actions reviewed by the FDA investigator were checked for effectiveness.

5) Failure to evaluate and investigate nonconforming product; and failure to adequately control nonconforming product. [21 C.F.R. 820.90 (a)] Specifically,

- Four of the seventeen device history records reviewed had out of specification results that were not evaluated, and the devices were further processed and released.

- Two of the eleven acceptance records for incoming product had out of specification results that were not evaluated, and the components were accepted.

- The FDA investigator observed two instances in which nonconforming product did not have a "hold tag," which is required by your firm's "Control of Nonconforming Product" procedure.

6) Failure to adequately inspect or test incoming product to verify conformance to specifications. [21 C.F.R. 820.80(b)]

Specifically, three of the eleven receiving records reviewed by the FDA investigator were incomplete.

7) Failure to evaluate potential suppliers and contractors. [21 C.F.R. 820.50(a)(1)]

Specifically, there were no documented evaluations for three of the four contractors/suppliers reviewed by the FDA investigator.

8) Failure to conduct quality audits to verify that the quality system is effective in fulfilling your firm's quality system objectives. [21 C.F.R. 820.22]

Specifically, your firm has not conducted an internal audit since your Quality Audit procedure was implemented in 2001. The inspection revealed that you have started conducting an audit, but only three of the identified twenty-three areas have been audited.

9) Failure to adequately implement your management review procedures. [21 C.F.R. 820.20(c)]

Specifically, your procedure requires you to conduct management review meetings biannually. Your firm has only conducted one meeting (8/8/07) since the procedure was implemented in 2003.

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 applications for Class III devices to which the Quality System regulation deficiencies 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 within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct these noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation for the corrective actions 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 Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the content of this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may forward a facsimile to her at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of 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 to bring your products into compliance.

Sincerely,

/S/

Carol A. Heppe
District Director
Cincinnati District

Warning Letter Response

- Troy Innovative Instruments, Inc. Response Letter