Innovative Sterlization Technologies LLC 3/2/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
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Cincinnati, OH 45237-3097
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March 2, 2016

WARNING LETTER
CIN-16-485178-10

VIA UPS

Scott E. Cohen
Chief Operating Officer
Innovative Sterilization Technologies, LLC
7625 Paragon Road, Suite A
Dayton, OH 45459-4063

Dear Mr. Cohen:

During the inspections of your firm located in Dayton, Ohio,on August 4-13, 2015 and October 6-November 4, 2015, investigators from the United States Food and Drug Administration (FDA) determined that your firm is the specification developer of the ONE TRAY Sealed Sterilization Container. 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 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 your response dated August 19, 2015, concerning our investigators' observations noted on the Form FDA 483, List of Inspectional Observations (FDA 483) that was issued on August 13, 2015; and your response dated November 10, 2015, concerning our investigators' observations noted on the FDA 483 that was issued on November 4, 2015 to the FDA 483. 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 establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). Specifically, your "Corrective Action" and Preventive Action" procedures, both dated December 22, 2014, are inadequate in that:

    a. They do not address analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems. The procedures also do not address employing appropriate statistical methodology, where necessary, to detect recurring quality problems.

    Additionally, your firm has not identified data sources and data analysis is not being conducted.

    b. Your firm has not adequately implemented your procedures in that you have not verified and validated corrective actions to ensure that such actions are effective and do not adversely affect the finished device.

    For example, CA05-2015 states that your contract manufacturer will move the process of manufacturing the filter covers in house, because the "slide bars on the filter covers appear to hang up after use…". The "Verification and Actual results" section states "Function check is being performed at final inspection". There is no documentation describing the functional check, no verification test data showing this action corrected the problem, and no documentation showing the effectiveness of the change was verified.

Your response, dated August 19, 2015 is not adequate. Your new Corrective and Preventive Action procedure, Rev 02, does not address the statistical methodology that will be used to analyze your data sources. Additionally, you do not address conducting a retrospective review of these data sources to determine if there are any existing and potential causes of nonconforming product or other quality issues that have not been identified. Also, you do not address performing a retrospective review of CAPAs to determine if verification/validation and effectiveness checks must be completed.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a)(1). Specifically, your firm assumed design control responsibilities and began making design changes to the ONE TRAY Sealed Sterilization Container (ONE TRAY) in December of 2014. You have not established the following design controls:

a. Failure to establish and maintain a Design History File (DHF) for each type of device to demonstrate the device was developed in accordance with the approved design plan and the requirements of 21 CFR part 820.30 , as required by 21 CFR 820.30(j). Specifically, the ONE TRAY's DHF is incomplete in that it does not contain or reference the following records: a design plan, risk analysis, design review(s), design validation and design transfer documents.

b. Failure to establish and maintain adequate procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). Specifically, you have not implemented your SOP 7.3.7 "Engineering Change Notification" in that verification and/or validation activities are not being performed.

For example, ECN-007, dated 3/30/15 changes the key hole slot width and radius on the filter slide for better alignment and less side-to-side movement within the bridge guide. Your Verification 13, dated 5/1/15 does not document the design method used for testing, the date of testing, the actual test results and the individual performing the test. The only verification documented is the "Verification Activity" section states "Physical movement of Slide Bar.", and the "Result of the Verification Activity" section states "Slide Bar moves less and has better alignment/engagement of filter screw.".

c. Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriates stages of the device's design development, as required by 21 CFR 820.30(e).

d. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g).

e. Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h).

Your response, dated August 19, 2015 is not adequate. You state you will be performing a retrospective review of ECN-007 and 008 to document the verification and/or validation to show the design changes did not have an adverse effect on the device. A retrospective review of all changes should be performed to assure the change was verified and/or validated.

Your November 10, 2015 response cannot be assessed at this time. Your response states you are developing design procedures for design validation, risk analysis, design transfer and design review. It also states that you have requested validation data from the 510(k) holder. Please provide an update on the progress of these corrective actions.

3. Failure to establish and maintain adequate procedures for receiving, reviewing, evaluating, and investigating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically,

Your "IST CUSTOMER COMPLAINT PROCEDURES/WORK INSTRUCTIONS", 2.16.15 Rev 4, is not being implemented in that warranty repairs that meet the definition of a complaint are not documented and investigated per your complaint procedure. None of the 134 warranty repairs received between 1/27/2014 and 8/3/2015 were evaluated as possible complaints. For example, warranty repair, RTM#20150213, dated 2/17/2015, states in the "Description of damage or warranty work needed" section, outer lid gasket/water channel filler was coming loose. In the "Description of repair or solution and testing section", it states outer lid gasket/water channel filler was replaced and tray was checked over. This warranty repair was not reviewed to determine if it meets the definition of a complaint and no failure investigation was documented.

Your response, dated August 19, 2015 cannot be assessed at this time. Your response states a retrospective review of all warranty repairs will be reviewed to determine if they meet the definition of a complaint. If it meets the definition of a complaint, it will be added to your complaint file. Please provide an update on the progress of these corrective actions.

4. Failure to establish and maintain procedures for changes to a specification, process, or procedures, as required by 21 CFR 820.70(b). Specifically,

On or about 5/12/2014, you had your contract manufacturer change from using Computer Numeric Control process to a hydroforming process to manufacture the ONE TRAY. You have not established process change procedures nor has this change been documented and verified/validated.

Your November 10, 2015 response cannot be assessed at this time. Your response states that you will fully document the validation activities performed to support the new manufacturing process; and will update your agreement with the contract manufacturer to address process changes. Please provide an update on the progress of these corrective actions.

5. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. Specifically,

Your "Supplier Selection Process procedure, Rev (1), dated 12/19/2014, and "IST SUPPLIER ORDER PROCESS" procedure, dated 6/06/2014 Rev -0-, does not address that services are evaluated and approved prior to use. For example, the firm contracted to validate the shelf-life and sterility results of the ONE TRAY were not evaluated or approved under your purchasing controls.

The corrective action in your August 19, 2015 response appears adequate.

Our inspection also revealed that your ONE TRAY Sealed Sterilization Container are also misbranded within the meaning of section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 C.F.R. Part 806 – Reports of Correction and Removals regulation. Significant deviations include, but are not limited to the following:

Failure to submit a written report to FDA regarding the correction that your firm made to the ONE TRAY Sealed Sterilization Container, as required by 21 C.F.R. Part 806.10. In January of 2014, you relabeled all customers' One Tray devices, because there was a typo on the labeling for the gravity cycle. The cycle should state 17-34 minutes, but it stated 10-34 minutes. This correction was initiated to remedy a violation of the Act caused by the device which may present a risk to health.

Your August 19, 2015 response appears 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 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 that 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: Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about the content of this letter please contact Ms. Brackett at (513) 679-2700, ext. 2167, or by facsimile at (513) 679-2773.

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 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/
Steven B. Barber
District Director
Cincinnati District

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