DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	9/3/2019-9/10/2019* FEI NUMBER 3006894945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anthony D. Biscotti, President

FIRM NAME	STREET ADDRESS
ONC Solutions Incorporated	5 Robinwood Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Acton, MA 01720-4427	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, the firm has not tested product bioburden on its X-Mark Fiducial Marker, part number 001007, a permanently implanted Class II medical device, since July 2013. The firm has determined that the X-Mark Fiducial Marker may be adopted into its contract sterilizer's (b) (4) sterilization cycle based in part on bioburden levels. The firm's Bioburden procedure, SOP-029, Rev 01 states, "(b) (4) bioburden samples are required for (b) (4) product families listed in SOP-028 Sterilization and Expiration Dating. Select (b) (4) samples of product from (b) (4) product family." The 2013 bioburden testing included (b) (4) test articles. This is a repeat observation from the previous FDA inspection.

Specifically, the firm approved adoption of the X-Mark Fiducial Marker, part number 001007, into its contract sterilizer's (b) (4) sterilization cycle but could not provide adequate justification for why the contract sterilizer's product is equivalent to or more challenging to sterilize than the X-Mark Fiducial Marker.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sara M Onyango, Investigator	x Sara Onyango	9/10/2019

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Specifically, the firm does not review batch sterilization records prior to releasing each lot of X-Mark Fiducial Marker, part number 001007. The firm's President stated his final acceptance activities include a (b) (4) inspection of the product and review of the supplier's Certificate of Conformance, which does not specifically reference sterilization activities.

Specifically, the firm does not have a written agreement that outlines responsibilities such as complaint handling, design changes, and recall authority with the company it identifies as being the manufacturer of the X-Mark Fiducial Marker, part number 001007.

OBSERVATION 2

Procedures to control environmental conditions have not been adequately established.

Specifically, the firm's President stated he implements measures to control particulates and microorganisms during in-process inspection of the X-Mark Fiducial Marker subassembly, part number (b) (4) including the use of (b) (4) (b) (4) however, this procedure is not adequately documented. The firm could not provide justification for why these measures are sufficient to control particulates and microorganisms.

OBSERVATION 3

Individuals who conduct quality audits have direct responsibility for the matters being audited.

Specifically, the firm's President stated that he conducts all internal audits for his company; however, he also stated he directly oversees all aspects of the quality system.

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OBSERVATION 4

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, a Material Review Report (MRR) was not issued per Non-Conforming Material procedure, SOP-033 Rev 01, for part number (b) (4) the subassembly for the X-Mark Fiducial Marker associated with Lot (b) (4) This is a repeat observation from the previous FDA inspection.

***DATES OF INSPECTION**

9/03/2019(Tue), 9/04/2019(Wed), 9/05/2019(Thu), 9/09/2019(Mon), 9/10/2019(Tue)

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Annotations to Observations

Observation 1: Promised to correct within 10 Weeks

Observation 2: Promised to correct within 5 Weeks

Observation 3: Promised to correct within 20 Weeks

Observation 4: Promised to correct within 2 Weeks

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."