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	7/24/2019-8/15/2019* FEI NUMBER 3009424796

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher J. Breault, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Kelyniam Global, Inc.	97 River Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Collinsville, CT 06019-3246	Medical Device 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 control environmental conditions have not been established.

Specifically,

A) The manufacture of cranial and craniofacial implants is in close-proximity to the cleaning process for these devices and in the same room, and visible particulates were observed in both the manufacturing and cleaning area during the inspection of this room. For example, during manufacture of the cranial implant, an employee was observed placing tools and (b) (4) then placing a cleaned implant, CSI020619-JB2, directly on the tray to dry. While the implant was drying, the employee (b) (4) that was filled with manufacturing particulates.

B) (b) (4) has not occurred to evaluate the environmental conditions of the manufacturing/cleaning room and there are no controls in place to ensure that the cleaning area stays free of particulates that may affect the (b) (4).

C) Your firm has (b) (4). There are no procedures regarding the proper sequence of gowning and the proper use of gloves to handle cranial implants.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey J Thibodeau, Investigator	X Jeffrey J Thibodeau Investigator Signed By: Jeffrey J. Thibodeau -S Date Signed: 08-15-2019 13:35:35	8/15/2019

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D) During the manufacture of implant CSI020619-JB2, a final inspection was observed as not being performed to verify that the device (b) (4), as required by your firm's finished device specification outlined in QSP4-4240 (b) (4).

OBSERVATION 2
Procedures for acceptance of incoming product have not been adequately established.

Specifically, your firm's specification for (b) (4) used in the manufacture of cranial and maxillofacial implants was not established as follows:

A) Your firm has found inclusions ((b) (4)) during the inspection of (b) (4) of (b) (4) as documented on NCR 05-00002, and has not updated your firm's specification, (b) (4). The NCR states that implants with (b) (4), however lot 58499526 of (b) (4) to manufacture cranial implants without routine documentation of such inspection. Supplier of (b) (4) stated that this phenomenon cannot be 100% avoided and is not able to be detected in their quality inspection.

OBSERVATION 3
A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the cleaning validation for cranial and craniofacial implants does not evaluate for potential contaminants outside of bacterial endotoxins.

***DATES OF INSPECTION**

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7/24/2019(Wed), 7/25/2019(Thu), 7/30/2019(Tue), 8/01/2019(Thu), 8/13/2019(Tue), 8/15/2019(Thu)

AMENDMENT 1

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

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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."