DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/25/2017-5/1/2017*
	FEI NUMBER 3003631996

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Thierry M. Giorno , CEO

FIRM NAME	STREET ADDRESS
Intra-Lock International	6560 W Rogers Cir Ste 24
CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33487-2746	TYPE ESTABLISHMENT INSPECTED 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 for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

a) Conclusion of complaint investigations are provided but there is no evidence or documentation of the investigation performed to reach the determined conclusion result. For example, the investigation result documented on Complaint #0111979, database #00457, originated on 05/12/2016 due to broken implant, states “Overdenture implants can break when forces/stress is too great for various users and patient related reasons. Forces/stress can be too great including that the denture must be properly relined to ensure excessive force is not applied to the implants.” However, there is no evidence of the investigation performed for this complaint to determine how the investigation result for this complaint was determined for this particular implant breakage.

b) Complaint #0112203, database #00517, initiated on 12/22/2016 due to implant failure was closed on 01/13/2017 without the documentation of the investigation and MDR evaluation performed by your QARA on Complaint Form #QA-85-03-01.

c) Your firm was informed by a sales associate that a wrong screw was placed in the IFONT package, Lot #BO137, on 12/08/2015. Your firm determined that a total of (b) (4) packages of this product had been

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	Karen M Rodriguez, Investigator 5/1/2017 X Karen M Rodriguez Karen M Rodriguez Investigator Signed by: Karen M. Rodriguez -S	5/1/2017

distributed prior to receiving this information. This alleged deficiency of the finished device contents in the packaging was not documented or investigated as a complaint. Your firm documented this issue as a non-conforming product under NCR #018 to document the re-work activities performed. However, an investigation was not performed and an assessment of the impact on the affected units on the field was not performed.

OBSERVATION 2

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

Specifically, you have not implemented your non-conforming product procedure titled "Control of Nonconforming Product", QOP-83-01, Rev. B, effective date 5/22/2014, Section 5.3 to determine the need for an investigation in that:

a) Non-conforming report (NCR) #018 was initiated on 12/10/2015 due to wrong screw (Part #IML99-01) on package of IFONT, Lot BO137. NCR #018 was initiated to document update to the Bill of Material (BOM) of the IFONT product to change the screw part number from ILM99-01 to IML99-02 and re-work activities to include screw part #IML99-02. No investigation was performed to determine the root cause for packaging the product using a wrong screw and no change order document was created and approved to document this change of the BOM. As a result of a lack of an investigation the products were incorrectly re-worked. Your firm later determined that the changes to the BOM and re-work activities documented in NCR#018 should not have occurred and on 02/10/2016 another NCR #019 was issued to document re-work activities of the IFONT devices to revert the BOM to include original screw part # IML99-01 and re-package the finished device product with the screw # IML99-01.

b) Non-conforming report (NCR) #022 was initiated on 12/15/2016 due to implant bottles not properly torqued by the (b) (4) line. The NCR documents the affected products were re-worked by re-packaging the bottles using a different (b) (4) line. This NCR was closed on 01/23/2017; however, there is no determination of a need for an investigation nor documentation of an investigation performed to determine the reason the packaging line did not properly apply the required

torque to the caps to fully seal the bottles, or documentation that indicates if any corrective/preventive actions were taken to correct this deficiency of the (b) (4) packaging line.

OBSERVATION 3
Procedures for corrective and preventive action have not been adequately established.

Specifically,

a) your corrective and preventive action procedure titled "Corrective and Preventative Action", QOP-85-04, Rev. D, effective 11/21/2016, is not adequate in that your procedure does not require CAPAs to be verified and/or validated prior to implementation.

b) the following CAPAs are not adequate:

i. CAPA 106 was initiated on 07/10/2015 due to vial missing implant. The CAPA does not have an adequate root cause and verification/validation of correction implemented was not documented. The Root Cause states "Need to **investigate.** There is a sensor on our robotic packaging machine that is supposed to detect an empty vial and stop the machine." Actions implemented included correction of (b) (4) camera and a weighing step to detect unfilled vials. However, verification for this correction prior to implementing corrective actions was not documented.

ii. CAPA 107 was initiated on 07/17/2015 due to doctor unable to open the implant vial. Root cause states "Cap may be too tight when inserted over the clear tube." Action implemented including update to the engineering drawing to increase the dimension of the caps. The CAPA states that on 06/10/16 the updated caps were received and were "much better." This correction was not verified/validated prior to implementation. During the inspection, I was informed the corrective action did not prove to be effective and the firm continues to investigate and make corrections to the cap but have not documented these actions and as a result the firm re-opened this CAPA on 04/27/2017 to document current investigation and corrections.

iii. CAPA 108 was initiated on 08/31/2015 due to vial missing implant. The CAPA root cause states "The table supporting the clear vials with the implants is made of aluminum, it vibrates as the robot is functioning. This vibration may be causing the smaller implants to vibrate out of the

clear vials." The CAPA presents corrections performed by (b) (4) to trays and adjustment to (b) (4) camera; However, CAPA 108 does not have evidence of verification/validation performed prior to implementation.

OBSERVATION 4
Procedures for design change have not been established.

Specifically,

a) neither your design control procedure titled "Design Control Procedure", QOP73-01, Rev. 12, effective date 11/19/2015, nor your design change procedure titled "Change Control", QOP-42-02, Rev. 1, effective date 10/19/2016" require validation or where appropriate verification of design changes before their implementation.

b) you performed a design change to the cap size of the primary packaging (vials) of your dental implants to increase the diameter of the caps as a correction to CAPA #107. As a result, you updated the engineering drawing #370/507/Blank, Revision B1 to Revision C2 to indicate dimension change from (b) (4) " to (b) (4) ". However, this design change was not documented and approved as per your design change procedure titled "Change Control", QOP-42-02, Rev. 1, effective date 10/19/2016, and this design change was not validated. In addition, results of the measurement verifications performed on the updated caps were not documented either.

OBSERVATION 5
Procedures to control environmental conditions have not been adequately established.

Specifically, you have not implemented your cleanroom certification and environmental monitoring procedure titled "Certification of Cleanrooms", QOP-64-02, Rev. B, effective date 5/19/2016, in that you did not perform the Viable and Non-Viable testing on a (b) (4) for (b) (4) and did not perform trending of data to define Alert and Action levels. This testing was performed (b) (4) on 04/20/2016, 11/28/2016, 04/12/2017.

AMENDMENT 1

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OBSERVATION 6

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

Specifically, you did not implement your supplier evaluation procedure titled "Supplier Evaluation and Monitoring", QOP-74-01, Rev. E, 12/18/2014 in that:

a) you have not performed (b) (4) audits of your contract manufacturer and contract sterilizer as per Section 2.5 of your supplier evaluation procedure.

b) you did not perform the (b) (4) supplier performance monitoring for 2016 period as per Section 2.1 of your supplier evaluation procedure.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct
Observation 5: Promised to correct
Observation 6: Promised to correct

***DATES OF INSPECTION**

4/25/2017(Tue),4/26/2017(Wed),4/27/2017(Thu),4/28/2017(Fri),5/01/2017(Mon)

AMENDMENT 1

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