DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	9/12/2016-9/14/2016
	FEI NUMBER 3002249830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Nikolaos Andreoulakis , Site Manager

FIRM NAME	STREET ADDRESS
Isolux, LLC	1045 Collier Center Way Ste 7
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Naples, FL 34110-8475	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 quality audits have not been adequately established.

Specifically, your firm's written internal audit procedure in the Quality System Regulation Manual (QSRM), Rev. 5, dated 11/10/2015, Section 1.10, is inadequate in that it does not provide requirements to ensure all applicable quality system requirements are reviewed, that quality audits are conducted by individuals who do not have direct responsibility for the matters being audited, corrective action(s), including a reaudit of deficient matters, are taken when necessary, and the report of the results of each quality audit and reaudit(s) are reviewed by management having responsibility for the matters audited. In addition, your firm has not implemented your internal audit procedure since your firm has not conducted any internal audits to date.

This is a repeat observation listed as Observation #6 on the previous FDA 483 issued on 01/22/2010.

OBSERVATION 2

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 in Section 4 "Purchasing" of the Isolux LLC Quality System Regulation Manual (QSRM), Rev. 5, dated 11/10/2015 in that:

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Karen M Rodriguez, Investigator 9/14/2016 X Karen M Rodriguez Karen M Rodriguez Investigator Signed by: Karen M. Rodriguez -S	9/14/2016

a) you did not document the evaluation of any of your current suppliers and contractors on file as required by your current procedure, with the exception of your ~~power supply~~ fiber optic cable supplier; and
b) your purchasing documents do not have an agreement that your suppliers and contractors agree to notify you of changes in the product or services so that you may determine whether the changes may affect the quality of a finished device.

This is a repeat observation listed as Observation #6 on the previous FDA 483 issued on 11/06/2015 and Item #2 in Warning Letter dated 01/08/2016.

OBSERVATION 3
Written MDR procedures have not been developed.

Specifically, your MDR procedure "MDR Reporting Procedure", SOP 12.0, Rev. 0, effective date 01/24/2006, is inadequate in that it does not include:

a) definitions of medical device reportable event and malfunction;
b) electronic reporting requirements and instructions;
c) reporting time frame of 5 business days when requested in writing by FDA; and
d) MDR Decision Tree is incorrect and may lead to not reporting a MDR event.

OBSERVATION 4
Procedures for design change have not been adequately established.

Specifically, your design change procedure in Section 2 of the Isolux LLC Quality System Regulation Manual (QSRM), Rev. 5, dated 11/10/2015, does not include requirements for validation or verification.

This is a repeat observation listed as Observation #3A on the previous FDA 483 issued on 11/06/2015.

OBSERVATION 5

AMENDMENT 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, your complaint handling procedure in Section 12 of the Isolux LLC Quality System Regulation Manual (QSRM), Rev. 5, dated 11/10/2015, provides requirements to evaluate complaints to determine if the complaint represents an event reportable to the FDA under the Medical Device Report regulation, but you do not have a mechanism to document this evaluation. You identified the "RMA Form" as the form used to document all complaints and investigations, but this form does not include provisions to document the MDR evaluation and your firm does not have any other form to document the required MDR evaluation for each complaint received.

OBSERVATION 6

Procedures or instructions for verifying that servicing meets specified requirements have not been adequately established.

Specifically, your servicing procedure in Section 13 of the Isolux LLC Quality System Regulation Manual (QSRM), Rev. 5, dated 11/10/2015, does not provide specified requirements and/or instructions for performing and verifying the serviced devices to ensure they conform to specified requirements. For example, devices for which the power supply is repaired or replaced requires passing a burn-in test prior to returning the unit to the customer, but this required test is not in your servicing procedure.

OBSERVATION 7

Procedures for training and identifying training needs have not been established.

Specifically, your firm does not have a written procedure to identify training needs, to ensure all personnel are trained to adequately perform their assigned responsibilities and are trained to the most current version of their respective procedures, and to document training. Your current "Training Program – Log", Rev. 1 , dated 01/21/2010 is limited to document training given to new production employees. In addition, your assembly employee responsible for performing receiving acceptance activities does not have documented training on the new incoming acceptance procedure "Incoming Materials Receiving Inspection Procedure", SOP 5.0, Rev. 0, effective date 11/06/2015.

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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*
Observation 7: *Promised to correct*

AMENDMENT 2

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Karen M Rodriguez, Investigator	9/14/2016 X Karen M Rodriguez Karen M Rodriguez Investigator Signed by: Karen M. Rodriguez -S	9/14/2016

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."