DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	7/23/2019-8/14/2019* FEI NUMBER 1000221205

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark Kaforey, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Xodus Medical Inc	702 Prominence Dr
CITY, STATE, ZIP CODE, COUNTRY New Kensington, PA 15068-7052	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

A validated process was not reviewed and evaluated and revalidated when changes or process deviations occurred.

Specifically,

The (b) (4) , used in your production operation (b) (4)

On 12/20/2017, maintenance operations were conducted to (b) (4) used for packaging and (b) (4) . You did not review and evaluate, and revalidate your production process for sealing when changes and process deviations occurred.

OBSERVATION 2

Complaints involving the possible failure of a device, labeling and packaging to meet any of its specifications were not reviewed, evaluated and investigated where necessary.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Dennis R Hock, Investigator	X Dennis R Hock Investigator Signed By 2000754886 Date Signed 08-14-2019 08:56:24	8/14/2019

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Returned Goods Authorizations (RGA), documenting information involving possible failure of a device, labeling and packaging to meet any of its specifications were not reviewed, evaluated and investigated where necessary. Additionally, the RGA's are not all shared or provided to the department responsible for evaluating complaints.

OBSERVATION 3

Production processes were not conducted, controlled and monitored to ensure that a device conforms to its specifications.

Specifically,

On 12/20/2017, maintenance operations were conducted to (b) (4) used for packaging and (b) (4) used in your production process. The (b) (4) was not revalidated after maintenance.

On the following dates, you received complaints for (b) (4) surgical devices:

8/28/2018	Complaint #651	Insufficient Heat Seal
12/04/2018	Complaint #663	Insufficient Heat Seal
1/22/2019	Complaint #668	Insufficient Heat Seal
5/07/2019	Complaint #681	Insufficient Heat Seal
6/20/2019	Complaint #685	Insufficient Heat Seal

In addition, you received Returned Goods Authorizations (RGA's) for (b) (4) surgical devices that were not documented as complaints.

6/12/2017	RGA #692	Documents "various" lots

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6/16/2017 RGA #686 Lot #15NOV03A

3/07/2018 RGA #778 Lot #17DEC08

Your production processes were not conducted, controlled and monitored to ensure that a device conforms to its specifications.

OBSERVATION 4

Products that do not conform to specifications are not adequately controlled.

Specifically,

The (b) (4) , used in your production operations to (b) (4) surgical device, (b) (4) Lots manufactured between 12/19/2016 and 12/20/2017, were not inspected to determine conformance. These Lots were subsequently released and distributed.

OBSERVATION 5

Complaint files are not maintained.

Specifically,

Between 11/01/2016 through 7/25/2019, you received 452 Returned Goods Authorizations (RGA) for all products manufactured. These RGA's are not all shared or provided to the department responsible for evaluating complaints. As such, the RGA's were not reviewed and evaluated to determine if the reported failures required documenting a complaint.

OBSERVATION 6

Corrective and preventive action activities and/or results have not been documented.

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Specifically,

The (b) (4), used in your production operations to (b) (4) surgical devices, (b) (4) was causing (b) (4). On 12/20/2017, after making production and process changes, a CAPA investigation was not initiated to determine corrective and preventative action activities and/or results.

OBSERVATION 7

Procedures for rework of nonconforming product have not been established.

Specifically,

During manufacturing you (b) (4) product. It is common practice to remove these non-conforming products from their failed packaging to be (b) (4), prior to determining a disposition. You do not have established procedures for (b) (4).

***DATES OF INSPECTION**

7/23/2019(Tue), 7/25/2019(Thu), 7/30/2019(Tue), 8/14/2019(Wed)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

Observation 6:

Observation 7:

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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."