DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	1/13/2020-1/16/2020
	FEI NUMBER 3006515340

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark L. Hair, Chief Intergration Officer

FIRM NAME	STREET ADDRESS
Venus Concept Inc	128 Baytech Dr
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95134-2302	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

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

Specifically, your firm's procedure titled, **Corrective and Preventative Action, SOP-1052, Revision: K** states in part "CAPA plans are expected to be closed in (b) (4) days however in some cases the analysis or implementation of the CAPA plan may require an extended period to complete. In this event, an explanation/justification is documented in the file." The procedure also mentions the firm's goals for CAPA completion milestones are as follows:

Initial Risk Assessment	(b) (4)
Containment	days
Corrective Action	days
Preventative Action	days
Effectiveness Check	days
Closure	

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EMPLOYEE(S) SIGNATURE
Marcia G Evans, Investigator - Dedicated Device Cadre

X Marcia G Evans
Investigator - Dedicated Device Cadre
Signed By: Marcia G. Evans -S
Date Signed: 01-16-2020 14:38:05

DATE ISSUED
1/16/2020

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I reviewed 12 CAPAs from May 2017 - present. During my review I observed that 8 out of 12 corrective and preventative action reports were not adequate according to your procedure.

a) 2 out of 12 CAPAs have been logged into system but have not been investigated for months

b) 5 out of 8 of your firm's CAPAs were not processed and closed out in the time frame outline in your procedure

c) 7 out of 8 CAPAs are missing investigation details and/or explanation of why CAPAs needed time frame extensions as required in your procedure

OBSERVATION 2
Complaint files are not adequately maintained.

Specifically, your firm's procedure titled, Incident/Event (Complaint) Handling, SOP-1126, Revision: T states in part "All Restoration Robotics employees are required to immediately report within (b) (4) to QA/RA or Customer Service any written, electronic, or verbal report that alleges product deficiencies related to the identity, quality, durability, reliability, customer dissatisfaction, safety, effectiveness and/or the performance of a Restoration Robotics products and/or services after it is released for distribution. Complaints may be sent to firm's complaint website, via telephone, via (b) (4) or to QA/RA Management.

I reviewed 13 complaints from May 2017 - present. During my review I observed the following:

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a) 1 out of 13 was a delayed in QA/RA reporting the complaint in a timely manner

b) 1 out of 13 that was received several months ago has not been investigated

c) 4 out of 13 complaints were missing investigation details

d) 3 out of 13 complaints were marked "no" for malfunction evaluation when in fact the device was found to have malfunctioned

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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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."