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 oradevices2firmresponse@fda.hhs.gov	11/8/2021-11/12/2021* FEI NUMBER 3016249968

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel F. Justin, CEO

FIRM NAME	STREET ADDRESS
Engage Uni LLC	3505 Lake Lynda Dr, Suite 206
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32817-8324	TYPE ESTABLISHMENT INSPECTED Specification Developer and Complaint File Establishment

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 WE OBSERVED:

OBSERVATION 1

Procedures for acceptance activities have not been adequately established.

Specifically,

Your firm's machining and finishing supplier for (b) (4), (b) (4), and (b) (4) failed to identify results of in-process inspection that deviated from the specifications documented on the inspection form, and these out of specification measurements were subsequently unidentified during DHR review conducted by your firm upon acceptance of finished devices. All samples from Lots (b) (4) and (b) (4) of (b) (4), Part No. (b) (4) measured below the specification indicated for "Item #2," and were identified as "Accepts," in the supplier's provided manufacturing records.

Additionally, your firm did not document Deviation PD01184, which initiated a change in the visual inspection procedure of implants, in the DHR reviews conducted for Lots (b) (4) and (b) (4) of (b) (4), Part No.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emma R Schaefer, Investigator Brandon P Thompson, Investigator	X Emma R Schaefer Investigator Signed By: Emma R. Schaefer -S Date Signed: 11-12-2021 10:42:22	11/12/2021

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(b) (4) This deviation was included in the manufacturing records provided by your firm's cleaning, packaging, and sterilization supplier, which were subject to DHR review.

OBSERVATION 2

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

Specifically,

Your firm does not have procedures established for the trending and evaluation of quality data to identify potential causes of nonconforming product or quality problems. Additionally, your firm has not conducted trending of quality data during 2021 for the purposes of identifying potential causes of nonconforming product or quality problems by means of the CAPA subsystem.

***DATES OF INSPECTION**

11/08/2021(Mon), 11/09/2021(Tue), 11/10/2021(Wed), 11/12/2021(Fri)

X Brandon P Thompson
Investigator
Signed By: Brandon P. Thompson -S
Date Signed: 11-12-2021 10:43:18

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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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."