DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/12/2018-2/15/2018
	FEI NUMBER 3008448733

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Delphine Molinari Allard , Quality & Regulatory Affairs Director

FIRM NAME	STREET ADDRESS
Cair LGL	RN6 Parc Tertiaire Du Bois Dieu, 1, Allee Des Cheveuilus
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Civrieux d Azergues, Lissieu, 69380 France	Cair LGL

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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

While reviewing customer complaint data complaints that showed the potential of a malfunction in a marketed medical device to cause injury, illness, or death if the issue were to reoccur were not reported within thirty 30 days as required.

Numerous complaints involving the delayed or inadequate (b) (4) due to (b) (4) (b) (4)) or related products were not reported as serious medical device reportable events. These complaints included (b) (4) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Eric M Padgett, Investigator X Eric M Padgett Investigator Signed By: Eric M. Padgett -S Date Signed: 02-15-2018 05:07:10	2/15/2018

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OBSERVATION 2

Complaint files are not adequately maintained.

Specifically,

Your firm has failed to review and evaluate complaints in a timely manner in order to determine the need to report serious issues and MDR events. The vigilance determination for complaints (b) (4) were found to be between 1 and 212 days past the 30 day reporting requirement. Some of these events were found to be reportable events as shown stated in observation number 1.

OBSERVATION 3

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

Specifically,

You have failed to document complaint data appropriately in order to conduct complaint data trending in a way that accurately represents the available complaint data. Reported complaints may reference numerous device malfunctions. However, complaint trending at your facility fails to account for a single received complaint notices referencing multiple device malfunctions.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct

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