Health Canada Santé Canada

Medical Devices Inspections - Central
Regulatory Operations and Enforcement Branch
201 – 370 Speedvale Avenue West
Guelph, ON N1H 7M7

Sent by Email

November 12, 2019

File number: HC6-61-8258-1

Glia Inc.
54 Craig Street
London, ON N6C 1E8
Company's email: tarek@tarek.org

Attention: Mr. Tarek Loubani, Owner

Subject: Inspection Final Report

Dear Mr. Loubani,

On November 5, 2019, an inspection of your establishment was conducted under the authority of the ***Food and Drugs Act*** (***Act***) to verify compliance with the ***Act*** and the ***Medical Devices Regulations*** (***Regulations***).

As a result of this inspection, the above noted establishment has been assigned a Compliant (C) rating, meaning that at the time of the inspection, the regulated party has demonstrated that the activities it conducts are in compliance with the *Food and Drugs Act* and its associated Regulations. A Compliant rating does not mean that there are no observations or corrective actions required.

The findings of the inspection were discussed and presented as a Draft Inspection Report at the closing meeting held on November 7, 2019. The attached Inspection Exit Notice documents the observations noted during the inspection that have been categorized according to Health Canada's Guide-0079 "Guidance on Risk Classification of Medical Device Observations". This guide is available on our website at:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0079_ris_class-eng.php

The report indicates that a response is expected by December 12, 2019. Your response should include a corrective action plan which addresses each observation and the preventive action taken to prevent recurrence. A timeline for completion should also be included. Health Canada is to be notified upon completion of the plan indicating that all observations have been addressed.

Failure to address observations in a satisfactory manner may lead to enforcement action as specified in the Medical Device Compliance and Enforcement Directive which can be found on the Inspectorate website at:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui_0073_tc-tm-eng.php

If you disagree with the content of the Final Inspection Report, you have five (5) business days to bring your concerns to the attention of the Operational Manager of the Health Products and Food Branch Inspectorate in your region. If you exercise this option, please do so in a written submission outlining the basis of the dispute citing the specific sections of the Final Inspection Report that are contentious. It should be noted that only information presented at the time of inspection will be considered.

I would like to thank you for the cooperation extended throughout the inspection.

Yours truly,

Digitally signed by cheng, zhihui
DN: C=CA, O=GC, OU=HC-SC, CN="cheng, zhihui"
Reason: I am the author of this document
Date: 2019-11-12 10:24:58

Zhihui Cheng

(Encl: Final Inspection Report)