01- Cover Letter & Executive Summary

Cover Letter

To Whom It May Concern:

Please find enclosed our application for a Medical Device Investigational Testing Authorization. Please do not hesitate to contact me at tarek@tarek.org or 519-488-6475 with questions regarding the application.

Regards,

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Executive Summary

Pulse oximetry is an important tool used to assess a patient's oxyhemoglobin saturation and it increases patient safety by alerting physicians to hypoxemia. Unfortunately, the costs of both the simplified and extended devices are prohibitive and reduce availability in smaller centres and poor countries, putting millions of patients in danger of easily treatable and preventable conditions. The technologies involved in the manufacture of a pulse oximeter are widely known and have no active patents covering them.

The Glia Inc. Pulse Oximeter is a device developed using current rapid prototyping technologies including 3D printing. The aim of Investigational Testing of the Glia Inc. Pulse Oximeter is to collect clinical data to be used in support of a medical device licence application to Health Canada with the goal of Health Canada approval of the manufacture and distribution of the Glia pulse oximeter. The aim of the project is to provide free and open access to plans and software of the Glia Inc. pulse oximeter, allowing physicians around the world to build a Health Canada approved pulse oximeter that meets USA Food and Drug Administration (FDA) 501(k) certification for use in their clinic or operating room.

This Investigational Testing Authorization application sets out the details of our proposed clinical performance testing of the Glia Inc. The Pulse Oximeter will be compared with arterial hemoglobin oxygen saturation (S_aO_2) as measured by blood gas analysis. Performance testing comparing the calibrated Glia pulse oximeter to the current gold standard pulse oximeter will also be performed.

For the investigation comparing the Pulse Oximeter with compared with arterial hemoglobin oxygen saturation as measured by blood gas analysis, the study design follows a standard protocol as recommended by the FDA. Study participants will have a radial arterial catheter inserted for SaO_2 measurements. Both the Glia Inc. Pulse oximeter and the gold standard pulse oximeter will be applied to the patients fingers applied to adjacent fingers on contralateral arm. Under careful monitoring, oxygen saturation level will be decreased with gas mixtures of progressively decreasing oxygen and increasing nitrogen to a safe and pre-defined end point. Performance testing comparing the calibrated Glia pulse oximeter to the current gold standard pulse oximeter will involve contemporaneous measurements of oxygen saturation from both oximeters to enable direct comparison of the two oximeters.