Santé Canada Health Canada

Therapeutic Products Directorate
11 Holland Ave
Address Locator: 3002A
Ottawa, ON K1A 0K9

19 October 2017

Application No. 271803

Olivia Sobczyk
Lab Manager
Thornhill Research Inc.
210 Dundas St. W., Suite 200
Toronto ON M5G 2E8

Re: Investigational Testing Application – Class II , Request for Additional Information

Dear Olivia Sobczyk:

This is in reference to your application for Authorization to conduct Investigational Testing in Canada, received on 22 August 2017, and submitted pursuant to Part 3 of the *Medical Devices Regulations*. This application pertains to the following:

Protocol: Calibration and validation of High Quality Low-Cost 3D Printed Pulse Oximeter

Date: 17 August 2017 (version 1)

Device: RA-MR System

Pursuant to Section 84 of the *Medical Devices Regulations*, we request the following information:

1. The protocol makes reference to the randomized control trial; however, by reviewing the information in the protocol there is no randomization in the study design. Confirm the type of study design that will be conducted and revise the protocol, as required. Provide redlined and clean copies of the revised protocol.

2. There is a discrepancy in the duration of the study in the protocol and the screening deficiency response letter. Revise the protocol to include the correct timeframe. Provide redlined and clean copies of the revised protocol.

3. In the screening deficiency response letter there is a timeframe for the treatment and follow-up schedules; however, these are not included in the study procedures of the protocol. Confirm if there is any follow up for this study. If so, the protocol should be revised. Provide redlined and clean copies of the revised protocol.

4. The protocol makes reference to the low-cost 3D printed pulse oximeter, which is an investigational device. Confirm where the device is manufactured and by whom, what materials are used in its manufacture, and if the device has been granted any authorization in Canada.

5. Confirm which control pulse oximeter(s) will be used. Provide the name(s), manufacturer(s), and Canadian medical device licence number(s).

In accordance with the Therapeutic Products Directorate policy entitled *Management of Applications for Medical Device Licences and Investigational Testing Authorizations* dated April 6, 2001, failure to provide a complete response to this request within sixty (60) days will result in the issuance of a refusal letter.

Please provide your written response to:

Information Dissemination Unit
Licensing Services Division
Medical Devices Bureau
11 Holland Ave
Address Locator: 3002A
Ottawa, ON K1A 0K9

NOTE: Your response may be submitted by e-mail to device_licensing@hc-sc.gc.ca, or sent by mail to the address above on a CD or DVD if it is too large to be sent by e-mail. Please refer to the following notice for the required format: http://web.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/ita-notice-nonectd-aee-avis-eng.php

If you have any questions regarding this request, please contact me, Manager, Investigational Testing & Special Access Division, at 1-613-946-6554.

Yours sincerely,

Bisi Lawuyi
Manager
Investigational Testing & Special Access Division
Medical Devices Bureau

BL/cd