

Therapeutic Products Directorate  
11 Holland Ave, 2<sup>nd</sup> Floor  
Address Locator: 3002A  
Ottawa, ON K1A 0K9

12 February 2018

**Application No. 279782**

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

**Re: Investigational Testing Application - Class II, Screening Deficiency Letter**

Dear Olivia Sobczyk:

This is in reference to your Application for an Investigational Testing Authorization for the Ra-Mr System received on 1 February 2018 and submitted pursuant to Part 3 of the *Medical Devices Regulations*.

Pursuant to the requirements of Part 3 of the *Medical Devices Regulations*, the following information is considered to be deficient and is required before your application can be accepted for review:

1. Please revise Section 3 of your application form to include a brief description of the objectives/aim of the protocol, as well as the intended use statement for the device.
2. Confirm whether an Investigational Testing Authorization has been obtained for the low-cost 3D printed pulse oximeter and provide the application number.

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 fifteen (15) days will result in the issuance of a rejection letter. Please provide your written response to:

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

**NOTE:** Your response may be submitted by e-mail to [device\\_licensing@hc-sc.gc.ca](mailto: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-mpps/prodpharma/activit/announce-annonce/ita-notice-nonectd-aee-avis-eng.php>

If you have any questions regarding your application, please contact Bisi Lawuyi, Manager, Investigational Testing & Special Access Division, at 1-613-946-6554, or by e-mail at: [Investigational\\_Testing@hc-sc.gc.ca](mailto:Investigational_Testing@hc-sc.gc.ca).

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Bisi Lawuyi', with a stylized flourish at the end.

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

BL/jfl