#2 Response to IRB
Date: 10/28/2020

1. Please include the word of mouth script in part A of the Subjects, Inclusion, and Exclusion Criteria section.

I assume you mean part A of the Recruitment & Compensation section, as part A of the Subjects, Inclusion, and Exclusion Criteria section is a drop-down option.

2. In part L of the device section, while water may not be available to subjects, for labeling purposes, is it a hazard to put the device in water? Could that hurt someone or could impact the integrity of the device?

This section of the application has been modified to add clarity.

3. A correction to my previous statement about including children in this study: since this is not a clinical study you can simply state "not applicable."

Section F of the "Subjects, Inclusion, and Exclusion Criteria" has been modified accordingly. The inclusion and exclusion requirements in the application and the informed consent form are modified to exclude minors and only include healthy adults between the ages of 18 and 40.

4. The intent of this device is not clear as different sections throughout the submission list different intents. Please see below and reconcile as these intents do not match.

The intent of this device is clarified in the different sections of the application.

> **--- Research Design section, question D: the intent of the device is to "provide the sensing ability to those who have lost their sensing ability in their hand."**

The intent of this device was clarified in this section.

> **--- Investigational Medical Device section question E: the intent of the device is to "rapidly assess physical measurements that subjects with nerve damage, prosthetic usage, and the loss of feeling in a hand are not able to detect."**

The intent of this device was clarified in this section.

> **--- Investigational Medical Device section questions A and U state this device is a diagnostic (you claim that the device is Exempt under 21 CFR 812.2(c)(3) which initially states that the device must be a diagnostic). However, this submission does not state what this device is diagnosing and question A of the same section states that this device is not diagnosing anything.**

The intent of this device is clarified in these sections. It is not a diagnostics device.