

Device Statement

The wearable sensor glove, or the measurement device, that we will develop as our prototype, will not pose any risk to the human skin. The subject will wear the wearable sensor glove like one would wear a normal glove. The wearable sensor glove is a noninvasive device that will be worn by the subject to measure the physical interactions between the subject's hand and their surroundings. The device will be made from a wearable fabric, and subjects will be selected to ensure that the subject is not allergic to the fabric material. The wearable sensor glove will be attached to the subject's hand using an elastic band around the wrist to prevent the glove from falling off the subject's hand. Our device will be qualified for exemption from the FDA's device regulations under category 3 (see 21 CFR 812.2(c)(3)).

This type of measurement device has already demonstrated its usability with human subjects in a similar study (references: Francés, Leire et al. "Design and Development of a Low-Cost Wearable Glove to Track Forces Exerted by Workers in Car Assembly Lines." *Sensors* (Basel, Switzerland) vol. 19,2 296. 13 Jan. 2019, doi:10.3390/s19020296) This device will not be designed to treat, cure, or diagnose any disease or ailment. This device is used as a measurement device to record temperature, pressure, and strain in a completely non-invasive manner.