

From: Stephen Lee

To: Behnam Ghaffari

Date: February 22, 2016

Subject: FCC File No. 0202-EX-ST-2016

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Message:

Hi Mr. Ghaffari,

1) We are asking for 300 because this is a disposable device that is 1 time use. Fifty units are, unfortunately, not adequate. When the clinician first applies the device, s/he has to ensure that it is positioned properly to obtain physiological signal on the chest. Since body types and skin types are different, the clinician is given several devices to check for optimal placement. If the initial placement is not deemed adequate, the device is removed from the body and unused (since it is a 1 time use device and has touched skin). Only 1 device will ultimately be used per patient but we are allotting several devices per subject so that the strongest signal can be detected. All devices (those that are used on patients, and those that were applied on skin but not used are returned to us for disposal).

2) This is not a market study. It is a technical feasibility study.

3) Yes we retrieve all devices.