Home Well Trading Ltd.

Omar Hodge Building Road Town,
Tortola BVI

September 20th, 2018

Sensifirm device - Attestation letter

To whom it may concern,

I am the chairman of Home Well Trading Ltd., the manufacturer of the Sensifirm device (FDA Listing # D301244, produce code PBX, GEI.)

The Sensifirm device holds FDA Clearance, under Premarket Submission Number K170637, and its dedicated safety and efficacy clinical trial report # RD 12049 E0, which demonstrates the safety of the subject device including the exposure to its radio frequency energy for therapeutic purposes.

Citations below refer to the document "'sensiFirm' Safety and Efficacy Study – A Five Months Report, RD 12049 E0" previously submitted in this exchange.

As part of the clinical trial, reviewed and approved by the FDA, the thermal effects of the RF exposure were discussed and investigated (paragraphs 3, 4, 4.3) using temperature measurements of an agar model of human tissue. A primary end point of safety was defined and fulfilled (paragraphs 5.2, 6.1). The 33 participants were monitored for potential side effects by the clinical trial principal investigator during the treatment period (paragraphs 5.9), as well as during the follow up period (paragraphs 5.10), for a total of five in person clinical examinations per participant.

We respectfully submit this evidence in the FDA report to demonstrate compliance with the Federal Communications Commission's rules for RF Exposure under 47 CFR § 1.1307 (c) and (d).

Home Well Trading Ltd.

Josef Luzon
Chairman