Form 442 Question 7: Experimentation Description

0111-EX-PL-2014

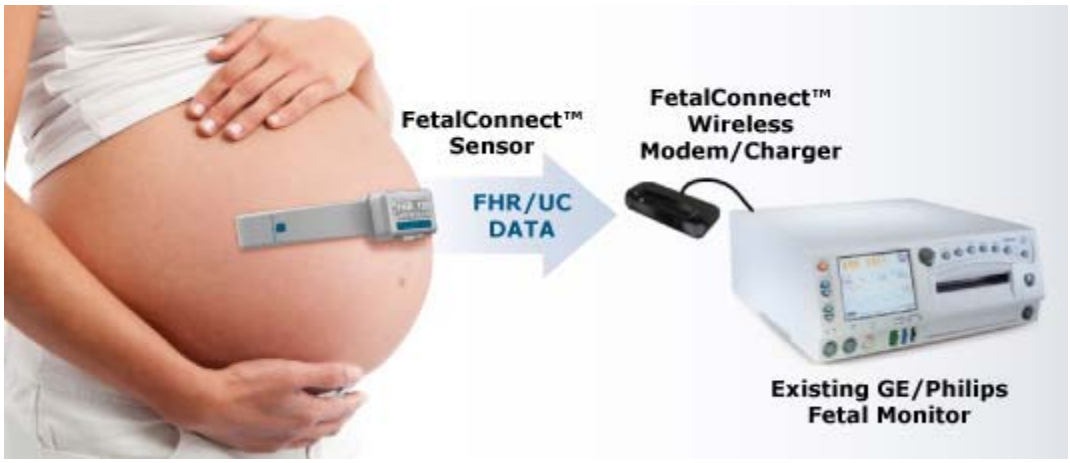
LifeWave Biomedical is planning to design and test a new UWB radar transceiver to ensure consistency with the FCC's UWB rules under Part 15.517.

Experiment overview

1) In conjunction with local California hospitals, demonstrate efficacy of UWB radar designs for purpose of intrapartum monitoring of fetal heart rate and uterine contractions, including:
    a. Assessing overall signal to noise ratio requirements across a range of patient body mass indices (BMIs).
    b. Demonstrating improvement in signal capture reliability and accuracy over the current care standards of Doppler Ultrasound and Toco sensors.
    c. Demonstrating non-inferiority with Doppler/Toco and identify BMI classes of superiority.

2) Test patients in comparison with gold standard (fetal scalp electrode and uterine pressure catheter) assessing non-inferiority and/or improvement over Doppler. (Example: superiority in signal capture but non-inferiority in accuracy)

3) Produce data sets of non-inferior/superior LifeWave vs. Doppler/Toco across a range of BMIs with a subset also having Fetal Scalp ECG and Intrauterine Pressure Catheter data.



FetalConnect™ Fetal Heart Rate and Uterine Contraction Monitoring System.