Category

Best Startup

Product/Solution Name

Lumerah

Date of Approval

N/A

Indications

National experts opine that the limitations of current fetal heart rate monitoring strongly suggest additional technologies are necessary to prevent neonatal metabolic acidemia, avoid newborn hypoxic brain damage and safely reduce the high rate of medically unnecessary C-sections. Each year, about 3 million women undergoing labor will have a fetal heart rate tracing with a nearly 90% false positive rate for detecting fetal hypoxic injury. Our unique non-invasive fetal oximetry system offers a significant opportunity to provide better care to these women and babies (as well as over 140 million women worldwide).

here are approximately 4 million childbirths annually in the USA and 7 million childbirths annually in the EU. We estimate that there are 40 million births in the devloped world and 100 million births in the developing world each year. These numbers are relatively consistent over a 10-year period.

There has been zero innovation in the fetal monitoring space in the past 20 years and the same CTG technology is used as the standard of care that was developed in 1958.

Therapeutic Categories

Medical Device for women and children's health

Background information and need for solution/product

Raydiant Oximetry, Inc has developed the Lumerah platform to more accuractely diagnose fetal distress during labor and delivery by non-invasively measuring the fetus's blood oxygen saturation. In a recently completed clinical study, Lumerah demonstrated an improved sensitivity and specificity for detecting fetal distress over the SOC. Lumerah has the potential to improve sensitivity over the SOC by 10% and potentially reduce newborn neurological injury by 10%. In addition, Lumerah has the potential to improve specificity over the SOC by 100% and potentially reduce emergency C-section rates by 50%.

We believe that Lumerah is posed to become the new standard of care for fetal monitoring during labor and delivery across the globe and has been granted breakthrough medical device designation by the FDA. The current standard of care (SOC) for fetal monitoring is CTF technology (cardiotocography) and has low sensitivity and low specificity for detecting fetal distress. Low sensitivity leads to the failed identification of the distressed fetus and leads to unrecognized newborn neurological injury. Low specificity leads unneceassary emegency C-sections, which carry risks to both mother and baby while driving up healthcare costs.

History of the development of the solution/product

Built a Gen 1 prototype in 2017 and established proof of concept in pregnant sheep.

Used Gen 1 to complete a proof-of-principle study to see if we could optically detect the fetal pulse and obtain the input for computational modeling:

PMID: 10958612
https://clinicaltrials.gov/ct2/show/NCT03013842

Build a Gen 2 prototype in 2019 to demonstrate more robust proof-of-principle study and inform hardware design
:
https://clinicaltrials.gov/ct2/show/NCT04081584

Build a Gen 3 prototype to complete a 30 patient pilot study to establish clinical proof of concept with a validated ground-truth measurement:

https://clinicaltrials.gov/ct2/show/NCT05147584

We are currently building a Gen 4 commercial product to test in an IDE pivotal study for regulatory submission.

Attached Files:

- Raydiant Oximetry Proof of Concept White Paper 2023.pdf

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

Traditionally pulse oximeters have been calibrated empirically with healthy volunteers briefly subjected to oxygen deprivation with simultaneous arterial blood gas measurements. This approach works because the relative size and shape of a human fingertip is similar between subjects.

For the transabdominal fetal oximetry application, the size and shape of pregnant abdomens is not similar between subjects, and it is not ethically feasible to deprive unborn fetuses in-utero of oxygen and simultaneously obtain arterial blood gas measurements from the baby.

To overcome these development challenges, we had to innovate new methodologies to calibrate pulse oximeters. We created a database of 7,014 virtual pregnant abdomens through computational modeling of photon propagation. Through these modeling platforms, we created 7,014 personalized calibration curves that would match all of the shapes, sizes and skin colors of the full-term human pregnancy condition. We refined the calibration curves through an iterative process until they experimentally matched in-vivo human data from pregnant women that was collected during feasibility studies. Then we trained a neural net through a process known as “supervised transfer learning” to teach the algorithm how to match the virtual data with actual patients. A foundation patent (US 11596361B2) covering these methodologies recently issues and we believe that these novel techniques will be generalizable to other diagnostic applications.

We validated this approach with the large animal pregnant sheep model and then subsequently with a 30-patient pilot study at UTMB in Galveston, Texas (NCT05147584). At the moment, we are adding noise models to the virtual calibration curves with the hopes of making the virtual data and virtual calibration curves indistinguishable from actual experimental data.
In the future with improved GPU processing power, we hope to create a personalized virtual calibration curve on the spot for that mother and baby, based on her individual size, shape and skin color. Today we reference the closest match from the 7,014 data sets. In the future, we believe that we will be able to create a personalized curve in real-time.

The development of these techniques has allowed us to overcome the challenges of innovating for pregnant women and we believe that these techniques can be used for other applications where collecting empirical data is costly or challenging.

Please provide appropriate references (ie Pubmed links)

Technical References:

PMID: 11092427
PMID: 32746021
PMID: 31945942

Preclinical Validation:

PMID: 14563919
PMID: 16009642

First-in-Human Feasibililty:

PMID: 15672014

Attached Files:

- 2021 Raydiant Oximetry White Paper.pdf