

World's first smartphone-based ultrasound imaging system cleared by the FDA

Mobisante, Inc., a privately held medical device company located in Redmond, WA, announced today that it has received 510(k) clearance from the FDA for its smartphone-based ultrasound imaging system, MobiUS.

MobiUS is an innovative mobile, affordable and accessible ultrasound imaging system that uses a smartphone and Internet cloud services. It is the world's first smartphone-based commercial ultrasound system.

The MobiUS system is indicated for ultrasound imaging, measurement and analysis of the human body for the following clinical applications: fetal/OB, abdominal, cardiac, pelvic, pediatric, musculoskeletal, and peripheral vessel imaging. Its compact size, portability and user interface enable it for use in primary and specialty care. Since MobiUS is based on smartphones it can leverage cellular networks or Wi-Fi to send images to a remote expert for diagnosis or second opinion, or to a Picture Archiving and Communication System (PACS) for storage.

"Meeting the FDA's rigorous standards of review is a critical milestone for Mobisante. We will now focus on launching MobiUS in selected markets and pursuing the CE mark in Europe," said Dr. Sailesh Chutani, CEO and co-founder of Mobisante.

MobiUS puts ultrasound capabilities into the hands of healthcare providers everywhere. This immediate access is especially important in rural communities in the U.S.A. and abroad that have limited resources, low population density, or are located far from the urban centers. "These systems are affordable enough that each of our clinics in rural eastern Washington could have one, which means we won't have to send our patients to facilities many hours away. Furthermore, since the devices are connected, it is easy to get a second opinion from remote experts," said Greg Brandenburg, CEO of Columbia Basin Health Association in Othello, WA. Brandenburg's clinics tested an earlier version of the device.

MobiUS represents a new class of "mHealth" devices being developed by Mobisante that are leveraging the smartphone as a computing platform. "MobiUS's progress is very exciting. Such connected devices can help save lives, fundamentally redefine health care and open up new revenue streams for the mobile ecosystem, including the mobile operators," said Chetan Sharma, president of Chetan Sharma Consulting and a recognized expert in the mobile industry.

Mobisante recently received seed funding from WRF Capital and was nominated by the GSMA for its 16th Global Mobile Awards. It has been featured on CNN, MIT Technology Review, Seattle Times, and Xconomy.

Mobisante, Inc. (www.mobisante.com) is a privately held mHealth product and services company whose goal is to make ultrasound imaging more accessible and affordable to help health care professionals practice better medicine and to reduce costs.

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