

## FDA Clearance Awarded to Calgary Scientific for Mobile Diagnosis on all Modalities



Calgary Scientific Inc., a company known for creating transformative technology for the medical industry and beyond, has announced their latest Class II clearance from the United States (US) Food and Drug Administration (FDA).

The leading enterprise image-viewing solution, ResolutionMD® is now cleared for diagnosis on mobile devices, for all imaging modalities (with the exception of Mammography).

Calgary Scientific worked closely with a number of Radiologists at a world renowned healthcare organisation to clinically validate the solution prior to submitting to the FDA. This builds upon their previous clearances for diagnosis using web, iOS and Android devices.

"We chose to implement ResolutionMD because it gives us the ability to quickly disseminate the images from our Pediatric Imaging Departments so that clinicians can provide the fastest and best care and treatment to our patients," said Stuart Royal, MS, MD, Radiologist-in-Chief at Children's Hospital of Alabama. "Their fully accredited, diagnostic image quality and secure solution gives us the flexibility to make clinical decisions from any device type, portable or desktop throughout our healthcare system and off-site."

The FDA's safety and effectiveness review of ResolutionMD found it to be substantially equivalent to PACS or dedicated diagnostic workstations, giving practitioners access to advanced image storage systems and diagnostic tool sets on-the-go. Gaining this clearance means a healthcare enterprise, across all departments, can feel confident in using ResolutionMD to perform a clinical diagnosis on web, iOS and Android devices, as it has been through a rigorous testing process, as agreed to by the FDA.

"We are excited to deliver this clearance to the institutions that rely on ResolutionMD to improve patient care", said Pierre Lemire, President and CTO of Calgary Scientific. "This is also an important advancement for all our valued partners including those who deliver custom-branded solutions, as they will be added under the Calgary Scientific registration with the FDA."

Source: Calgary Scientific

15 April 2014

Published on: Sat, 19 Apr 2014