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Calgary Scientific Receives 510K Clearance for Next Generation of ResolutionMD™, Calcium Scoring, and Coronary Analysis Products

Advanced visualization products on PureWeb™ and SDK platforms fully cleared under FDA's new elevated risk classifications

Calgary, Alberta – March 5, 2009 Calgary Scientific Inc., a leading innovator in advanced visualization solutions, has received 510K clearance from the United States Food and Drug Administration (FDA) for its next generation of ResolutionMD™, Calcium Scoring and Coronary Analysis advanced visualization products. Originally introduced and 510K cleared in 2007, this generation of ResolutionMD and cardiac clinical modules includes new efficient MIP/MPR and VR capabilities, proprietary 3D direct volume rendering techniques that provide best-in-class imagery, fully-automated rapid heart segmentation plus other functionality to improve the speed and accuracy to complete a study. All products can be delivered on Calgary Scientific's multi-patent pending PureWeb™ platform or via seamless integration into PACS, RIS or EHR using a software development kit. In addition, this clearance addresses the "moderate level of concern" classification for PACS and advanced visualization software established by the FDA in 2008. The increased rigor in this new clearance will set a higher standard for all companies in the advanced visualization space.

"The trend in PACS and advanced visualization is increasing sophistication in functionality and increasing reliance on these tools for primary interpretation of medical images by clinicians," stated Kyle Peterson, Calgary Scientific Director of Regulatory and Corporate Affairs. "The FDA is now applying a higher level of scrutiny including the requirement for more detailed documentation than they have in the past. Calgary Scientific is among the first advanced visualization companies to evolve its product realization processes to provide the level of risk analysis, design and testing documentation now required for 510K clearance."

"We are seeing tremendous interest and demand from both our OEM partners and from medical facilities in this next generation of ResolutionMD products" says Byron Osing, CEO and Chair at Calgary Scientific. "We have made significant investments in building a highly flexible, intuitive portfolio of advanced visualization products with extremely rigorous software development processes as this clearance attests and as such Calgary scientific is raising the bar for what can be expected from advanced visualization companies going forward. Delivered on our PureWeb platform or via a software developers kit, we are addressing the greatest of demands for accessibility and expanding the reach of medical imaging. We are very pleased that medical professionals on a global basis can benefit from our ResolutionMD products as they are now cleared by the FDA in the United States, Health Canada and CE Mark approved."

FDA 510K Cleared Products:

ResolutionMD

An innovative, fully web-based advanced visualization platform. ResolutionMD Web provides access to all original study images and powerful advanced visualization tools using only a browser on any computer or tablet, or personal device, without downloading any software or data onto the device.

Calcium Scoring

This module is used to quantify calcium in the coronary arteries as a predictive tool for future coronary events, such as a heart attack. It uses non-contrast-enhanced cardiac CT images. Some of the features

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will include single-click Agatston scoring, calcium pre-highlighting, and customizable reports that allow you to meet the needs of your practice.

Coronary Analysis

This module is used to visually inspect and quantify stenoses in the coronary arteries. MIP/MPR, 3D, curved MPR, and cross-sectional images enable flexible evaluation of arteries. Some of the features include automated centerlining that allows for efficient inspection of arteries in curved MPRs, heart segmentation, and centerline editing for getting through difficult stenoses.

About Calgary Scientific Inc.

Calgary Scientific is dedicated to providing advanced visualization solutions for medical imaging that improves the efficiency and quality of diagnosis made by imaging professionals. Calgary Scientific has a powerful portfolio of products that perform sophisticated image post-processing, including tools for 2D, MIP/MPR and 3D, a suite of cardiac modules for both CT and MR, and vessel analysis. Calgary Scientific also has proprietary intellectual property for image fusion, virtual colonoscopy and Computer Assisted Tissue Identification (CATI™). Calgary Scientific aims to be the premier provider of advanced visualization solutions in the medical imaging market. For more information on Calgary Scientific, go to www.calgaryscientific.com.

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