

Rcadia COR Analyzer® System Receives Expanded FDA Clearance to Rule Out Coronary Artery Disease in Coronary Branch Vessels

Newton, MA - February 9, 2011 - Rcadia Medical Imaging announced today that it has received FDA 510(k) marketing clearance for an enhanced version of its COR Analyzer® System to assess coronary branch vessels in addition to main coronary arteries in patients with suspected coronary artery disease (CAD). The clearance is the third for the COR Analyzer System, a unique clinical decision support tool that automatically detects significant (50 percent and over) stenotic lesions in coronary arteries from Coronary CT Angiography (cCTA) studies.

“The enhanced version expands the benefits of the COR Analyzer System as a powerful complement to cCTA in evaluating suspected CAD patients,” said Shai Levanon, President and CEO of Rcadia. “By providing rapid detection of stenotic lesions our system enables expanded use of cCTA to enhance patient care and reduce unnecessary costs.”

The FDA clearance follows the recent publication of the first clinical study evaluating the COR Analyzer’s enhanced version. The study, published (online) in *Academic Radiology* in January 2011 by researchers at Thomas Jefferson University, demonstrated that the “COR Analyzer provides a high negative predictive value for the absence of coronary disease in branch vessels as well as the major coronary arteries.”

The retrospective study, conducted by Ethan Halpern, MD, and David Halpern, compared 207 cases evaluated by the COR Analyzer System with expert interpretation. The final clinical interpretation identified 48 patients with significant (over 50 percent) stenosis. The COR Analyzer System demonstrated a sensitivity of 92 percent and a negative predictive value of 97 percent. In the study, the system’s specificity was 70 percent and the positive predictive value was 48 percent.

The investigators noted that the “high negative predictive value will be most useful in a population with a low prevalence of coronary disease - such as the emergency room chest pain population - where the COR Analyzer might be used to facilitate the rapid discharge of a majority of patients who have normal coronary CTA studies during all hours of the day or night.”

About Rcadia Medical Imaging

Rcadia Medical Imaging Ltd. develops and markets proprietary computerized systems that automatically detect clinical abnormalities in digital medical images, particularly for patient triage in emergency, life threatening conditions. The company’s first FDA-cleared product, the COR Analyzer® System, provides fully automated, real-time analysis of Coronary CT angiography to enable the practical application of cCTA in detecting significant coronary artery disease. The COR Analyzer improves the utility of Coronary CTA studies in the emergency department to triage chest pain patients and optimizes work flow in cardiology and radiology departments. Learn more at www.rcadia.com.