

Rcadia Cardiac COR Analyzer Receives FDA Clearance

HAIFA, Israel, Feb 14, Rcadia Medical Imaging, Ltd., developer of novel computer-aided diagnostic software, has received U.S. Federal Food and Drug Administration (FDA) clearance to market its COR Analyzer I , which assists screening of triage patients for coronary artery disease.

Coronary artery disease is a major underlying cause for acute chest pain in emergency room (ER) patients. Rcadia's COR Analyzer I and COR Analyzer II computer-aided diagnostic software packages use proprietary image processing algorithms to analyze coronary CT Angiography, CTA, studies to provide extremely fast and accurate identification of coronary artery disease.

In the U.S., more than 5 million patients present in the ER with acute chest pain each year. Identifying appropriate treatment causes a variety of clinical and work-flow difficulties. This is because missing clinically significant coronary artery disease can lead to morbidity, while misdiagnosing non-significant coronary artery disease leads to further, unnecessary cardiac evaluations.

“Particularly in the ER, adopting the Rcadia COR Analyzer software, which works hand-in-hand with CTA images, enables highly accurate identification of coronary artery disease as the cause for chest pain,” says Dr. Anna Chacko, vice chairman of the division of radiology at Boston Medical Center.

To determine whether chest pain was caused by coronary artery disease, Rcadia's COR Analyzer products automatically reconstruct and accurately analyze patient CTA images.

According to Dr. Chacko, “CTA is being rapidly adopted to triage patients in ERs across the U.S. Rcadia's COR Analyzer II can quickly identify coronary artery disease with a high degree of accuracy. Thus, it streamlines patient care and prevents unnecessary delays in diagnosis and treatment.”

In a recent pilot study, Rcadia COR Analyzer I and COR Analyzer II packages successfully identified coronary artery disease in 100 percent of patients, and 99 percent of the analyzed blood vessels.

“The real benefit of Rcadia's software is its high negative predictive (NPV) value”, explains Jeff Mendel, MD chair department of radiology at Caritas St. Elizabeth's Hospital in Boston. Dr. Mendel adds that high NPV is the key to screening because it identifies true negative tests and is highly reliable in ruling out coronary artery disease.

Regulatory notice: The COR Analyzer II is an investigational device and is not yet available for sales in the U.S.