

PMA P000041  
for  
RapidScreen RS-2000

A computer-aided detector (CAD) for identification of regions of interest (ROI's) on frontal views of plain Chest X-Rays (CXR's) to improve detection of Solitary Pulmonary Nodules (SPN's) that could represent lung cancer. The system brings the ROI's to the attention of users after the initial reading of the radiographs.

## Device Description:

The device consists of :

- Charged-coupled device (CCD) film digitizer (150 dpi, 12 bits)
- Barcode reader
- PC-based data processor (Pentium 2000 w Windows 2000)
- Detection algorithm (software package)
- Laser printer
- TFT flat panel color display monitor (1024 x 768 pixels)

## FDA Reviewers of P000041:

- Robert J. Doyle                      Lead Reviewer
- Joseph Jorgens, III                      Software
- Xuan Vo                                      Manufacturing
- Rachel Solomon, M.H.S.                      Bioresearch Monitoring
- Robert F. Wagner, Ph.D.                      ROC Analysis
- William Sacks, Ph.D., M.D.                      Clinical Studies
- Marina Kondratovich, Ph.D.                      Statistics