

Discussion Points for the
February 3, 2004 Panel Meeting

1. Please discuss whether the data in the PMA support the conclusion that the CAD can reduce observational errors by helping to identify overlooked actionable lung nodules on chest CTs. In particular, given that use of the CAD produced a statistically significant improvement in ROC performance, please discuss whether

- a. the use of an expert panel is appropriate for determining actionable nodules, given that a tissue "gold standard" is not feasible.
- b. actionable nodules are a reasonable target for a lung CT CAD to be judged safe and effective.
- c. the achieved gain in ROC performance demonstrates safety and effectiveness of the CAD.

2. Please discuss whether the labeling of this device, including the indications for use, is appropriate based on the data provided in the PMA.

3. Please discuss whether the sponsor's proposed training plan for radiologists is adequate. If not, what other training would you recommend?

4. If the PMA were to be approved, please discuss whether the above, or any other issues not fully addressed in the PMA,

- a. require post-market surveillance measures in addition to the customary Medical Device Reporting (MDR), etc.
- b. suggest the need for a postapproval study.