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## **RADIOLOGICAL DEVICES PANEL MEETING**

**March 5, 2001**

### **DISCUSSION POINTS FOR**

### **DEUS TECHNOLOGY, RAPIDSCREEN<sup>™</sup> RS-2000**

**P000041**

1. Please discuss whether or not you believe that the PMA contains sufficient data to conclude that the RapidScreen<sup>™</sup> RS-2000 can reduce observational errors by identifying overlooked cancers on chest radiographs, considering:
  - a) The reproducibility of the computer performance
  - b) The non-location-specific versus location-specific ROC and sensitivity/specificity results, and
  - c) In particular, the amount of incremental improvement shown
2. If you conclude the RapidScreen<sup>™</sup> RS-2000 helps to minimize observational errors by identifying overlooked cancers on chest radiographs, please discuss whether or not you believe that the PMA contains sufficient data to conclude this can be done without unacceptably increasing the number of patient work-ups.
3. Please discuss whether the labeling of this device, including the indications for use, is appropriate based on the data provided in the PMA. Consider as a minimum:
  - a) Ability to detect solitary pulmonary nodules
  - b) Ability to detect more 9-19 mm solitary pulmonary nodules using the device than when not using it, and
  - c) Ability to reduce the likelihood of missing small lung cancers, most of which are early stage cancers.
4. Based on the information shown in the PMA, were the film readers sufficiently trained in the use of the device before the with-CAD readings were made?
5. Do the above, or any other issues not fully addressed in the PMA need resolution before the PMA is approved, require postmarket surveillance or suggest a postmarket study?

March 2, 2001

March 2, 2001