DRAFT

Radiological Devices Advisory Panel Meeting

Tuesday May 23, 2006
Gaithersburg Holiday Inn, Gaithersburg MD

General Topic Discussion: Reclassification of Full-Field Digital Mammography Systems from Class III to Class II

The Food and Drug Administration (FDA) is proposing a <u>reclassification from Class III (premarket approval) to Class II (special controls) for Full-Field Digital Mammography Systems</u>. This reclassification is based on the fact that, to date, four FFDM systems, representative of the technology and physical characteristics of FFDM, have been approved under Premarket Approval Application (PMA). The Agency also established over time special controls based on physical measurements. The Agency believes this reclassification is also supported by the Digital Mammography Imaging Screening Trial (DMIST), which added evidence of the non-inferiority of FFDM system compared to the conventional mammographic examination.

1. Do you believe that the risks to health from the device have been identified and that the mitigations for these risks are appropriate?

   If not, what additional risks to health are presented by the device? What mitigations for these risks would provide a reasonable assurance of safety and effectiveness?

2. Do you believe that the information to be required for 510(k) clearance will be sufficient for determining substantial equivalence between a new device and the predicates?

3. Do you believe the materials presented support reclassification of FFDM devices?

4. If reclassified, are there any concerns that you believe need to be addressed in the labeling (includes direction for use, indications, and contraindications) of these devices?