

**DUKE UNIVERSITY MEDICAL CENTER**

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Division of Dockets Management (HFA-305)  
Food and Drug Administration,  
5630 Fishers Lane,  
Rm. 1061,  
Rockville, MD 20852

Ref: Comments on the Reclassification Proposal and Draft Special Controls Guidance Document for Absorbable Hemostats (Dockets 2006N-0362 and 2006D-0363)

As conference convener and on behalf of the conference participants, I am submitting a summary of the Absorbable Hemostat Consensus Conference entitled Regulation of Absorbable Hemostatic Agents: Guidance for Encouraging Innovation Without Compromising Patient Safety.

Please consider these in reference to the above referenced dockets and thank you for the opportunity to comment on this important matter. I would be happy to discuss this summary report with the FDA panel should any clarification be needed.

Sincerely,

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**2006N-0362****C 3**

**Regulation of Absorbable Hemostatic Agents: Guidance for  
Encouraging Innovation Without Compromising Patient Safety**

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