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10.11.2007

Dear Panel Member:

We seek your recommendation on the appropriate device classification of the absorbable hemostatic agent and dressing device intended for use as an adjunct to hemostasis during surgical procedures.

To assist in your preparation for the panel discussion, the following information is enclosed regarding this topic:

Tab 1: Device Classification/Reclassification Procedures

Tab 2: A memorandum describing the absorbable surgical hemostatic agent device, the reclassification process for previously classified devices and the proposed identification for the absorbable surgical hemostatic agent device.

Tab 3: Reclassification issues for the absorbable surgical hemostatic agent device.

Tab 4: Sample Guidance Document: *Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA*

Tab 5: Literature on the absorbable surgical hemostatic agent device.

Tab 6: Guidance Document: *The Least burdensome Provisions of the FDA Modernization Act of 1977: Concept and Principles; Final Guidance for FDA and Industry*

Tab 7: Sample Labeling for an Absorbable Hemostatic Agent: Surgifoam™ Sponge (Sterile) (absorbable gelatin sponge, USP)

If you need any additional information or clarification regarding the information provided in this panel pack, please contact me at 301-594-3090, extension 141.

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