



DUKE UNIVERSITY MEDICAL CENTER

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To whom it may concern:

In response to Docket No. 2006N-0362, I suggest that the FDA reconsider its proposal to reclassify absorbable hemostatic devices.

I have learned that the FDA proposed the reclassification of absorbable hemostatic devices from class III, requiring pre-market approval, to class II, special controls. If reclassified, these devices will no longer be required to undergo their current mandatory clinical evaluation for safety and efficacy. Consequently, they may be used in operating rooms without having undergone the clinical testing currently required and could impact surgical procedures as well as patient outcomes.

I understand that, in making this decision, the FDA did not obtain input from experts in vascular surgery, transplant surgery, cardiothoracic surgery, urologic surgery, or neurosurgery, even though hemostatic devices are used in great volume in and hemostasis is critical to these surgical areas.

Because new products may be cleared under the reclassification without indications for use that include common uses of current products, new and untested products may be used according to a surgeon's established practice, not as indicated in product labeling.

Finally, testing and labeling of hemostatic device interactions with disease states or anticoagulant drugs, is not described. This could impact surgical hemostasis.

Therefore, absorbable hemostatic devices should remain class III devices.

I appreciate your attention to his matter.

Sincerely,

David M. Albala, M.D.
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Director of Minimally Invasive and Robotic Urologic Surgery

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