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

To whom it may concern:

I am writing in regard to Docket No. 2006N-0362.

Upon learning that the FDA has recently proposed a rule that would reclassify absorbable hemostatic devices from class III devices requiring pre-market approval to class II, special controls, I wish to express my concern that new products will not receive proper clinical testing for safety and efficacy before reaching the operating room. This could impact both surgical procedures and patient outcomes.

It is my understanding that the proposed reclassification did not include input from vascular surgeons, transplant surgeons, cardiothoracic surgeons, or neurosurgeons who frequently use hemostatic devices in their practice, nor does the proposal describe testing or labeling to indicate the possible interactions of hemostatic devices with disease states or anticoagulant drugs, thereby potentially impacting surgical hemostasis.

Also, because new products may be cleared without indications for common uses of current products, such as in neurosurgery, surgeons may unintentionally use new products that have not been tested for that use according to their established practice.

I suggest that the FDA take these considerations into account and continue classifying absorbable hemostatic devices as class III devices.

I am grateful for your time.

Sincerely,

Craig P. Fischer MD, MPH, FACS Weill Medical College of Cornell University Department of Surgery

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