

UC Surgeons

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To whom it may concern:

Concerning Docket No. 2006N-0362, I am writing to suggest that that the FDA continue to classify absorbable hemostatic devices as class III rather than reclassify them as class II devices, thereby no longer mandating pre-market approval and clinical evaluation for efficacy and safety.

If reclassified, these devices could be used undergoing little or no clinical testing, impacting surgical procedures and, ultimately, patient outcomes.

It has come to my attention that, in making the decision to reclassify these devices, the FDA did not solicit the opinions of vascular surgery, transplant surgery, cardiothoracic surgery, or neurosurgery experts, despite their frequent use of hemostatic devices.

I am also concerned that some surgeons may continue using new and untested products according to their current practice, rather than as indicated in the new product's labeling because the reclassification could mean that new products will be cleared with indications for use that do not address some common uses of current products, such as neurosurgery.

In addition, the proposal does not include a description of testing or labeling that addresses potential interactions of absorbable hemostatic devices and anticoagulant drugs or disease states; because of this, surgical hemostasis could be influenced.

I appreciate your attention to these considerations and hope that the FDA will reconsider reclassifying absorbable hemostatic devices.

Sincerely,



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