The Center For General and Minimally Invasive Surgery

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To whom it may concern:

I am writing in reference to Docket No. 2006N-0362 to suggest that the FDA reconsider its recent proposal of reclassifying absorbable hemostatic devices from class III, requiring pre-market approval) to class II, special controls.

Class III devices undergo mandatory clinical evaluation to ensure that they are both safe and effective. Currently, that applies to absorbable hemostatic devices, but if the proposed reclassification takes place, new products may be used in operating rooms without undergoing clinical testing. This could impact surgical procedures in addition to patient outcomes.

I also understand that, despite the high-volume, critical use of absorbable hemostatic devices in vascular, transplant, cardiothoracic, or neurosurgery, the FDA did not solicit the input of experts in these surgical areas when considering the proposal to reclassify.

Testing and labeling that address the interactions of such devices with anticoagulant drugs and disease states are not described in the FDA's proposal, which could have an impact on surgical hemostasis. Also, the proposed regulatory process under reclassification could result in clearance of new products without indications for use of common uses of current products, such as in neurosurgery. Because of this, it is possible that surgeons could unintentionally not follow product labeling of new and untested products but instead use them according to established practice.

Thank you for your time and attention.

Sincerely,

Miguel R. Silva, MD

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