



*The* DEPARTMENT of NEUROLOGICAL SURGERY

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To whom it may concern:

In regard to Docket No. 2006N-0362, I am writing to suggest that the FDA should continue to classify absorbable hemostatic devices as class III devices, rather than reclassifying them as class II.

Hemostasis is a critical component of neurosurgery, yet it is my understanding that experts in these fields were not consulted by the FDA before the proposal to reclassify was made.

Because class II devices do not undergo the same mandatory pre-market approval as class III devices, they may be used in operating rooms without having undergone mandatory clinical testing to evaluate their safety and efficacy. This could have a negative affect on surgical procedures and, thus, patient outcomes.

In addition, the reclassification has the potential to prevent new products from including common labeling for use of current hemostatic devices, such as their use in neurosurgery. Hence, surgeons may use new, untested products according to established practice rather than labeled indication.

Furthermore, testing and labeling that address potential interactions of hemostatic devices in certain disease states or with anticoagulant drugs has not been described in this proposal, possibly influencing surgical hemostasis.

For all of these reasons, I believe it is important that the proposed reclassification be reconsidered and that absorbable hemostatic devices should remain class III devices. I appreciate your consideration of my concerns.

Sincerely,

Mark Shaffrey, M.D.

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