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Department of Otorhinolaryngology - 6663 7 JUN -4 A8 21  
Head and Neck Surgery

31 May 2007

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 Otolaryngology - Head & Neck Surgery. It is my understanding that experts in this field were not consulted by the FDA before the proposal to reclassify these products 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 negative impact 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 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,

A handwritten signature in black ink, appearing to read "BWO", with a large, sweeping flourish extending to the right.

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