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June 6, 2007

To whom it may concern:

This letter is in reference to Docket No. 2006N-0362. It has come to my attention that the FDA recently proposed a rule to reclassify absorbable hemostatic devices from class III (pre-market approval) into class II (special controls). Currently, class III devices are required to undergo mandatory clinical evaluation and pre-market approval to ensure their safety and efficacy.

I am concerned by this proposed change in classification of absorbable hemostatic devices because of the possibility that new products may enter the operating room with little or no clinical testing, which has the potential to impact surgical procedures and ultimately patient outcomes.

Based on my understanding, the FDA did not solicit input from experts in vascular surgery, transplant surgery, cardiothoracic surgery, or neurosurgery when considering this proposal, despite the high volume of use and criticality of hemostasis in these procedures. Additionally, the FDA has not described testing or labeling to address interactions of hemostatic devices with disease states or anticoagulant drugs, which could influence surgical hemostasis. Moreover, the proposed reclassification and regulatory process could allow new products to be cleared with indications for use that exclude some very common uses of the current products (ie, neurosurgery). I am concerned that some surgeons may unknowingly use the new and untested products according to their established practice, rather than as indicated in the product labeling.

Based on what I have discussed above, I would like to suggest that the FDA reconsider the reclassification of absorbable hemostatic devices and allow them to continue as class III devices. I appreciate your time and consideration regarding this matter.

Sincerely,

Marc H. Glickman, MD

Marc H. Glickman, MD, FACS
President

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