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B. JUSTIN KIM, M.D., F.A.C.S. K.H. LIM, M.D., F.A.C.S.

To whom it may concern:

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Re: Docket No. 2006N-0362

The FDA has recently proposed the reclassification of absorbable hemostatic devices from class III to class II. This change in classification could have serious deleterious effects in the outcome of patients undergoing procedures involving hemostasis.

Absorbable hemostatic devices were previously classified as class III, meaning that these devices were required to undergo clinical evaluation and pre-market approval. This process ensured that these devices were tested and deemed to be safe and efficacious. By changing the classification to class II, the possibility exists that novel products, not tested in the clinical setting, may well be employed in the operating room. This could impact the safety of surgical procedures, and more importantly, affect the well being of patients undergoing surgical procedures involving hemostasis.

Hemostasis is a critical part of many surgical procedures, including but not limited to neurosurgery, cardiothoracic surgery, and vascular surgery. However, to the best of my knowledge, leaders in these fields were not asked to supply information to the FDA as to the impact of this reclassification. Further, testing or labeling has not been described by the FDA to address the interaction of hemostatic devices with anticoagulant drugs or disease states. The proposed reclassification and regulatory process could let new devices be approved with indications precluding common uses of the device. This could have serious consequences if a surgeon inadvertently used a new device according to practice rather than the labeling.

Please take these points into account as you consider the reclassification of absorbable hemostatic devices. For the safety of surgical patients, they should remain as class III devices.

Thanks for your attention to this matter.

Sincerely,

B. Justin Kim, M.D.

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