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DEPARTMENT OF SURGERY

Please reply to:
HARBOR/UCLA MEDICAL CENTER
BOX _____
1000 WEST CARSON STREET
TORRANCE, CALIFORNIA 90509

June 6, 2007

Dear Sir or Madam:

I write regarding Docket No. 2006N-0362, the FDA's recent proposal to change the classification of absorbable hemostatic devices. These products are currently considered class III devices, requiring mandatory clinical evaluation before going to market. The proposed rule would reclassify these as class II, special controls that do not require the rigorous class III evaluation.

I hope that the FDA will reconsider the classification change, as several aspects of this are troubling. First, as I understand it, the experts who regularly perform surgical hemostasis, such as vascular, cardiothoracic and transplant surgeons, were not contacted to testify regarding the reclassification. Such testimony would have been invaluable in making this decision. Second, reclassification from class III to class II would mean that new devices could be used in a surgical setting without benefit of clinical testing. This could jeopardize surgical success and patient welfare. Finally, the FDA's recommended change in classification could create a situation whereby a new product could be released with narrower indications than devices currently available. While labeling would deter most surgeons from applying these devices incorrectly, the possibility exists that a surgeon would use a new product off the labeling, according to practice.

For these reasons, it would not be advisable to alter the classification of these devices. Absorbable hemostatic devices, so important to my work in trauma and cardiothoracic surgery, should remain under their current class III status, for patient safety.

Sincerely,

Handwritten signature of Timothy L. Van Natta in cursive.

Timothy L. Van Natta, M.D.
Division of Cardiothoracic Surgery
Division of Trauma and Critical Care

2006N-0362

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