



22 South Greene Street
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Dear Sir or Madam:

Re: Docket No. 2006N-0362

The FDA is proposing a change to the classification of absorbable hemostatic devices, namely a change from class III (pre-market approval) to class II (special controls). This proposed change, however, would mean that the clinical evaluation and pre-market approval currently in place to ensure the safety and efficacy of absorbable hemostatic devices would no longer be mandatory.

This change creates the possibility of untested devices entering the operating room, raising doubts over the safety of surgical procedures involving hemostasis and possibly placing patients undergoing these procedures at risk.

Hemostasis is a widely used and critically important technique in many types of surgery. Yet experts in the fields of transplant surgery, cardiothoracic surgery, vascular surgery, and neurosurgery were not contacted by the FDA to give counsel on the proposed change in classification. Further, the interaction of hemostatic devices with both disease states and anticoagulants has not been addressed by the FDA with either investigative tests or labeling. The change in classification and regulatory process means that new products could be introduced with indications that exclude common uses of the device. A surgeon could mistakenly use the novel device according to practice rather than following the labeling.

Due to safety concerns, absorbable hemostatic devices should remain in their current classification as class III devices.

Thanks for your consideration regarding this matter.

Sincerely,

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