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Medical Center



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May 29, 2007

E. Papavassiliou, M.D.  
Division of Neurosurgery

Federal Drug Administration  
%FAX: 301-827-6870

Dear Sir or Madam:

In reference to Docket No. 2006N-0362, I wanted to voice my concern over the FDA's recent proposal to change the classification of hemostatic devices from class III to class II. Whereas Class III devices must undergo rigorous evaluation in a clinical setting, class II devices are not required to undergo such evaluation. This proposed change in classification is alarming, as the lack of clinical testing means that a product could be used in operating room settings untested, possibly adversely affecting the safety of the procedures, and more importantly, patients' lives.

To the best of my knowledge, the FDA didn't consult leaders in the field—neurosurgeons, cardiothoracic surgeons, vascular surgeons or transplant surgeons—when making its decision, even though hemostasis is critical in their practice. Because of the proposed reclassification, new products could be approved with labeling that excludes some common indications. The FDA is relying on surgeons to follow the labeling of any new products; however, surgeons may instead follow their established practice. This represents a serious safety risk.

Please reconsider the proposal to reclassify hemostatic devices. In the interest of public safety, hemostatic devices should be class II devices, ensuring that they would still undergo evaluation in a clinical setting and thus be subject to the required testing that would confirm their safety and efficacy.

Many thanks for your time.

Sincerely,

E. Papavassiliou, M.D.

EP:imf

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110 Francis Street, Suite 3B  
Boston, MA 02215

(617) 632-7246  
fax (617) 632-0549  
epapavas@bidmc.harvard.edu