



January 26, 2007

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Rockville, Maryland 20852

**RE: Docket Number 2006H-0362
Proposed Reclassification of Absorbable Hemostatic Devices
Proposed Rule**

To Whom It May Concern:

These comments are submitted on behalf of Vascular Solutions, Inc., a leading manufacturer of state-of-the-art medical products including a variety of hemostatic devices comprised of collagen and/or gelatin in combination with a licensed biologic, bovine-derived thrombin.

We appreciate the opportunity to comment on the proposed rule published by the Centers for the Food and Drug Administration (FDA) on October 31, 2006, which discusses FDA's intent to reclassify absorbable hemostatic devices from Class III to Class II. See General and Plastic Surgery Devices; Reclassification of the Absorbable Hemostatic Device, 71 Fed. Reg. 63278 (October 31, 2006).

Vascular Solutions is supportive of FDA's reclassification proposal and generally believes that the special controls identified in the draft guidance document displayed in the associated Federal Register notice will provide reasonable assurances of the safety and effectiveness of absorbable hemostatic devices. See Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability, 71 Fed. Reg. 63774 (October 31, 2006). Please note that Vascular Solutions has submitted separate comments pertaining to the draft guidance document.

Vascular Solutions appreciates the opportunity to comment on this proposed rule and we are eager to provide FDA with any additional information that would enable the agency to complete the reclassification of the affected devices. If FDA staff would like to discuss these issues in detail, please do not hesitate to contact Deborah Neymark at (763) 656-4349.

Sincerely,

A handwritten signature in cursive script that reads "Deborah Neymark".

Deborah L. Neymark
Vice President, Regulatory Affairs, Clinical Research and Quality Systems