



05 June 2007

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1062  
Rockville, MD 20852

Regarding:

**Docket 2006N-0362:**  
General and Plastic Surgery Devices; Reclassification of the Absorbable Hemostatic Device

**Docket 2006D-0363:**  
Guidance for Industry and Food and Drug Administration Staff; Draft Class II Special Controls Guidance Document: Absorbable Hemostatic Devices

Dear Classification Panel:

HemCon Medical Technologies, Inc. appreciates the opportunity to provide feedback and comment on the proposed reclassification of the absorbable hemostatic device and the special controls guidance document that will make the reclassification possible. HemCon supports the reclassification because the benefit of providing new life-saving technologies outweighs the risks associated with a change in regulatory pathway.

A simple summary of that change in regulatory pathway, i.e., abbreviated 510(k) versus premarket approval submission, has two fundamental components: reduction in quality system review by FDA and reduction in the required human clinical data for *existing* technologies. Potential risks related to the proposed shift in oversight in both areas are more than adequately addressed in the proposed draft special controls guidance document.

First, in terms of quality system review, the Material and Performance Characterization requirements of Section 6 clearly require characterization of the raw material components of the device, including the source and purity of each component. In addition, characterization of the final device is required as well as

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release specifications. Submission of these quality system data mitigates the risk associated with a reduced quality system review.

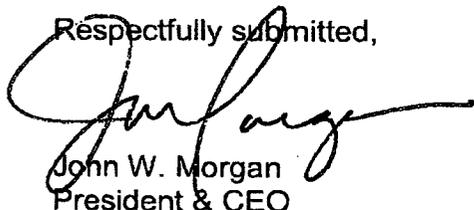
Second, in lieu of mandatory clinical studies, the draft guidance relies on well-designed bench and animal testing in side-by-side studies with predicated devices. However, contrary to some expressed concerns, it does not eliminate the need for clinical studies if the device has:

- indications for use dissimilar from legally marketed absorbable hemostatic device of the same type;
- designs dissimilar from designs previously cleared under a premarket notification, and/or;
- new technology, i.e., technology different from that used in legally marketed predicates.

HemCon can attest to this requirement. As a manufacturer of unique, proprietary chitosan-based hemorrhage control devices, HemCon made an inquiry concerning chitosan as new technology should reclassification occur and the draft guidance document become effective. The FDA response was that chitosan is considered new technology and clinical data would most likely be required (per CAPT Stephen Rhodes, then Plastic & Reconstructive Surgery Devices Branch Chief). This is a risk based approach that will reduce the burden for devices based upon existing technologies, yet still require clinical data for devices based upon new technologies. This approach mitigates the risk associated with not requiring clinical data for all new absorbable hemostatic devices.

In the risk management decision surrounding reclassification, the benefit of providing new and/or improved absorbable hemostatic devices to treat the risks associated with bleeding must be weighed against the risks of bringing those new devices to market sooner. HemCon believes the proposed Class II Special Controls Guidance Document: Absorbable Hemostatic Devices reasonably balances risks and benefits. Thank you for the opportunity to provide input.

Respectfully submitted,



John W. Morgan  
President & CEO

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