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**BY FACSIMILE**

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

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

**Docket 2006D-0363**: Draft Class II Special Controls Guidance Document: Absorbable Hemostatic Devices

Dear Sir/Madam:

On behalf of HemCon Medical Technologies, Inc. (HemCon), a manufacturer of hemostatic devices, we submit these comments in support of the FDA's proposal to reclassify absorbable hemostatic devices from Class III to Class II devices ("Reclassification Proposal") (see 71 Fed. Reg. 63728 (October 31, 2006)) and the Agency's related Draft Class II Special Controls Guidance Document for Absorbable Hemostatic Devices ("Draft Special Controls Guidance"). We appreciate the Agency's reopening of the public comment period until June 7th, 2007 and this opportunity to submit comments.

HemCon applauds the FDA's intent to implement the "least burdensome approach" to the development of safe and effective absorbable hemostatic devices. We believe the Draft Special Controls, with general controls, provide reasonable assurance of safety and effectiveness. In combination with the Agency's extensive experience with these types of devices, we believe the Draft Special Controls provide a flexible framework that will allow testing requirements, including clinical trials, to be matched to the risk associated with the new device.

Contrary to what some critics have claimed, we do not see the Draft Special Controls as a rigid blueprint that give all new absorbable devices a 'free pass' on clinical trials. Rather, the Draft Special Controls appropriately give the Agency the flexibility to match the animal *and human* model testing required to

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demonstrate safety and effectiveness to the risks associated with individual devices. In this scheme, "least burdensome" does not translate to "shortest path" but rather "most appropriate path." HemCon strongly supports this regulatory approach.

HemCon also respects the careful consideration the FDA has given to this issue and the extent to which the Agency has sought input from medical experts and the industry. The FDA's General and Plastic Surgery Devices Panel held a public meeting in July 2002 (the "2002 Panel") to discuss reclassification of absorbable hemostatic devices to Class II with special controls. The 2002 Panel tabled any action because they rightfully needed more information about what the special controls would be. At another public meeting of the Panel in 2003 (the "2003 Panel"), the FDA provided more information about the potential content of the special controls. After considerable discussion and input from manufacturers and the FDA, the 2003 Panel voted unanimously to reclassify absorbable hemostatic devices from Class III to Class II with a Class II guidance to be the special controls.

The FDA published its Draft Special Controls guidance in the Federal Register on October 31, 2006, three years after the 2003 Panel. Clearly, the Agency carefully considered the content of the Draft Special Controls. The potential risks were identified and the FDA appropriately recommended measures to mitigate those risks. In many cases, the risks may be addressed by animal model tests; in other cases, clinical trials will be required. This is not a 'one size fits all' approach. Rather, it is a risk-based, "least burdensome" approach and one we support.

FDA solicited public comments to the Reclassification Proposal and the Draft Special Controls until January 29, 2007. In response to requests for an extension in the comment period, on May 8th, the Agency reopened the comment period until June 7th. Thus, the Agency has been diligent in soliciting public comments to the proposed reclassification.

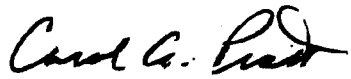
The vast majority of comments submitted in the initial comment period argued against the Reclassification Proposal. We find this bias disturbing. In general, the negative comments were submitted by parties with relationships to companies that have absorbable hemostatic devices that were approved as Class III devices through the PMA process. Essentially, critics argued that all new absorbable hemostatic devices should be required to go through the PMA process because human clinical trials are necessary to demonstrate safety and efficacy for all new absorbable hemostatic devices.

While this 'drawbridge' mentality may be understandable, we believe this view is overly burdensome and does not serve the public interest. The proposed

reclassification provides a flexible regulatory framework such that some new devices may require clinical trial testing while others may not. Existing materials that have been well-studied may be able to rely exclusively on animal model studies. In contrast, novel technologies, such as HemCon's chitosan-based hemostatic bandages, will require clinical testing. This is an appropriate "least burdensome" model that strikes the best balance between getting new devices to market as expeditiously as possible and ensuring that new devices are safe and effective.

In summary, HemCon strongly supports the FDA's proposal to reclassify absorbable hemostatic devices from Class III to Class II devices using the Draft Special Controls guidance as the Class II special controls. We believe this approach appropriately recognizes the FDA's extensive experience with hemostatic devices and materials and provides the Agency with the flexibility to determine the "least burdensome" path to demonstrate the safety and effectiveness of new absorbable hemostatic devices.

Respectfully submitted,



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CAP/mm

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