



Architects of the New Biomaterials Age

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VIA FACSIMILE
301-827-6870

April 27, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**RE: Comments on the Reclassification Proposal and Draft Special Controls
Guidance Document for the Absorbable Hemostatic Device**

Dear FDA:

Thank you for the opportunity to comment on the agency's proposed reclassification of absorbable hemostatic devices stated in the proposed reclassification notice (Federal Register, Vol. 71 (Oct. 31, 2006) 63728-63732).

Orthovita would generally like to express its support for the reclassification; however, Orthovita has the following comments on the reclassification and associated Class II Special Controls Guidance Document¹.

I. Definition of the Reclassified Category

As drafted, the proposed regulatory identification allows for hemostatic agents formulated from new materials to be marketed and cleared via the 510(k) process. Orthovita believes that absorbable hemostatic devices comprised of novel materials (e.g., materials not yet demonstrated to be safe and effective) and/or new devices with unique modes of operation should continue to require approval via the PMA process. The risks presented by any such new materials cannot be adequately assessed based on the history of use of current materials. At a minimum, FDA should require clinical data of these types of novel devices.

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¹ "Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Absorbable Hemostatic Device" issued on October 31, 2006.

II. Combinations of Licensed Thrombin and an Absorbable Hemostatic Device

Orthovita supports the FDA's position that combinations of licensed thrombin and an absorbable hemostatic device be reviewed under 510(k) per this proposed rule. We would also request that the FDA consider the least burdensome approach for combinations of unlicensed biological products such as unlicensed thrombin and an absorbable hemostatic device, in cases where the applicant is able to show substantial equivalence to licensed thrombin products via non-clinical and preclinical test methodologies and/or standard test methodologies.

III. Abbreviated 510(k) Pathway for Absorbable Hemostatic Devices

Orthovita believes that the traditional 510(k) is the most appropriate pathway for these devices because we feel that complete test reports and substantial data need to be included as part of these submissions. As such, Orthovita believes that the Abbreviated 510(k) pathway is not appropriate for these devices.

IV. Clinical Studies

Orthovita generally encourages FDA to consider the Least Burdensome Provision of the FDA Modernization Act of 1997 and limit the burden of clinical data requested to establish equivalence under this rule. However, Orthovita supports the agency's recommendation that clinical data be collected for an absorbable hemostatic device with indications for use dissimilar from legally marketed devices of the same type and/or designs dissimilar from designs previously cleared under a premarket notification and/or new technology. Orthovita also believes that clinical data should be considered for devices with novel materials; devices with unique modes of operation; and to support the following high risk indications: neurological, ophthalmic and urologic indications (see Labeling below).

V. Labeling

Orthovita believes that neurological, ophthalmic and urologic indications are indications with an additional level of risk. As such, we feel that the agency should require data that specifically and directly addresses these individual indications; or otherwise require a sponsor to specify that these indications be listed as exclusions in the labeling.

Orthovita is a medical device company offering advanced bone regeneration and soft tissue healing technologies. Our experience lies in developing and distributing novel, synthetic-based biomaterial products. Orthovita currently has four key commercial product platforms: Vitoss Bone Graft Substitute, Vitagel Surgical Hemostat, Cortoss Synthetic Cortical Bone (under IDE investigation; not currently approved for use in the United States), and Imbibe Delivery and Disposable Systems. Orthovita currently holds a PMA for the Vitagel Surgical Hemostat product.

Orthovita would like to thank the FDA staff involved in this reclassification effort and to especially recognize FDA staff member Dr. David Krause for his diligence with this project. We look forward to the expeditious publication of the final rule.

Please feel free to contact me with any questions you may have.

Regards,



Gina M. Nagvajara, Ph.D.
V.P., U.S. Regulatory Affairs

cc: David Krause, Ph.D. (FDA)