



Office of Combination Products  
WO 32, Room 5129  
10903 New Hampshire Avenue,  
Silver Spring, MD 20993

Food and Drug Administration  
Rockville MD 20857

October 22, 2010

Christine Kuo  
Director, Regulatory Affairs and Quality Assurance  
Skeletal Kinetics LLC  
10201 Bubb Road  
Cupertino, CA 95014

Re: Request for Designation  
SKaffold™ Bone Void Filler  
Our file: RFD100058  
Dated: n/a  
Received: September 13, 2010  
Filed: September 17, 2010

Dear Ms. Kuo:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for SKaffold™ Bone Void Filler (“Skaffold BVF” or “product”) that you submitted on behalf of Skeletal Kinetics LLC. As explained below, we conclude that the Skaffold BVF is a device that will be reviewed and regulated by the Center for Devices and Radiological Health (CDRH).

Description of the Product

According to the RFD, Skaffold Kit contains: Calcium phosphate powder, dilute sodium silicate liquid, and a mixing system (mixing bowl, pestle, and spatula).<sup>1</sup> The calcium phosphate powder and dilute sodium silicate liquid are packaged separately and are mixed by the end user prior to implantation. Skaffold is currently indicated to fill bony voids or gaps of the skeletal system (i.e., extremities, spine, pelvis).<sup>2</sup> The defect may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Skaffold is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. In addition to this cleared indication, you now

<sup>1</sup> The kit is available in three different sizes: 5cc, 10cc, and 25cc.

<sup>2</sup> The RFD states that Skaffold is a trade name of Callos® Bone Void Filler and the two have identical chemical and technological characteristics. They have been cleared by CDRH under 510(k) submissions K030554 and K051123. These bone void fillers are governed by 21 CFR 888.3045.

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propose to expand it to state that Skaffold is also intended "for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade."

You recommend that Skaffold for the proposed expanded indication be assigned to the Center for Devices and Radiological Health (CDRH) for premarket review and regulation because "it acts as a mechanical barrier or tamponade."

Product Classification: Device

We have considered the information in the RFD and discussed the issues with staff from the Center for Drug Evaluation and Research and CDRH. It appears from the data and theoretical calculations contained in the RFD that the calcium phosphate does not achieve coagulation through chemical or metabolic means. Consequently, based on the information in the RFD, FDA's current understanding of the product, and the published literature, we have determined that your product for the proposed expanded indication meets the statutory definition of a device.<sup>3</sup>

CDRH's Division of Surgical, Orthopedic, and Restorative Devices (DSORD) will have responsibility for the product's premarket review and regulation. For further information about review requirements and how to proceed, please contact Mr. Larry Coyne, Chief, DSORD, Restorative Devices Branch, at (301) 796-5650 or email him at [laurence.coyne@fda.hhs.gov](mailto:laurence.coyne@fda.hhs.gov). Please include a copy of this letter with your initial submission to CDER. For further information regarding regulation of combination products, please refer to the webpage for the Office of Combination Products (<http://www.fda.gov/CombinationProducts/default.htm>).

If you have any questions about this letter, please contact me at (301) 796-8938. Finally, the Office of Combination Products is available to you as a resource for questions or issues that may arise throughout the development of your product. You may reach us at the above address or by email at [combination@fda.gov](mailto:combination@fda.gov).

Sincerely,

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<sup>3</sup> See Section 201(h) of the Act which states that the term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

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A handwritten signature in black ink that reads "Leigh Hayes". The signature is written in a cursive, flowing style.

Leigh Hayes  
Product Assignment Officer

cc: Laurence Coyne