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Bio-Interfaces, Inc.
Pre Market Notification

ATTACHMENT IV

The calcium phosphate materials have a well-established biocompatibility profile, based on many years of clinical experience. The ability of calcium phosphate biomaterials in the size range of Bii-GRAFT™ to support bone adaptation is supported by many years of preclinical studies and clinical usage, demonstrating the attractiveness of such calcium phosphates as an endosseous implant material for filling and contouring osseous defects such as periodontal lesions. Such an indication represents a low- or no-load reconstructive or augmentation clinical condition.

Bio-Interfaces, Inc. has conducted a reasonable search of materials research and clinical experience from available published literature and oral communications and presentations at professional forums, as well as private communications with clinicians, regarding the performance of bioresorbable calcium phosphate bone graft substitute materials. Additionally, in-vitro characteristics have been performed and specifications developed for the Bii-GRAFT™ Bioresorbable Calcium Phosphate Particulate material. A review of available clinical results on similar materials indicate efficacy as a synthetic bone graft substitute material, when used in accordance with the guidelines provided in the Instructions for Use. We have concluded that the Bii-GRAFT™ Bioresorbable Calcium Phosphate Particles are substantially equivalent to the referenced devices and are safe and effective for their stated uses. Extensive literature citings have been included with this application.

Bii-GRAFT™ 6140 Bioresorbable Calcium Particles are substantially equivalent to allogeneic freeze-dried bone, Bii-GRAFT™ 1860, Osteograf-LD™ synthetic materials. The determination of equivalence has also been based on the chemical and physical characteristics of Bii-GRAFT™:

* Bii-GRAFT™ 6140 is an osteoconductive biomatrix that approximates the chemical constituent of natural bone. The physical form of the material is particulate particles in the range of 105-250μ. The nominal composition is 75 percent HA.

* Bii-GRAFT™ meets or exceeds specifications for trace elements and HA/TCP content (chemistry), as specified in ASTM F-1185 and F-1088, the Standard Specifications of Ceramic Hydroxylapatite and Tricalcium Phosphate for Surgical Implants.

* Trace element analysis of Bii-GRAFT™ indicates that the material is at or below the limits established in ASTM F-1088 and F-1185 for TCP and HA, respectively.

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* That sterilization or re-sterilization using the methods and cycles indicated have no significant effect on the material.

A reasonable attempt has been made to anticipate adverse safety and effectiveness conditions for the submitted device. Like any other implant, this type of bone graft substitute is susceptible to potential clinical problems, but it is believed that they are secondary to the response to the material itself. It is felt that some complications are a result of a failure to heed stated contraindications and practices dictated in the Instructions for Use. Such problems as migration, extrusion, dehiscence, sloughing, delayed healing, paresthesia, edema, hematoma, latent infection, inflammation and local and/or generalized allergic reactions can occur. Conditions such as wound breakdown and dehiscence many times can be traced to clinical placement errors, such as overfilling or failure to properly contain the particulate material after placement. Major load-bearing defects should not be filled with particulate grafting material and it is also important to place the particles in direct contact with bleeding bone. Care needs to be exercised in the use of the material to avoid surgical-related complications.