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USBiomaterials

Section X- 510(k) Summary

510(k) Summary Statement (as required by section 807.92(c)
Perioglas®-Bioglass® Bone Graft Particulate

Trade Name : Perioglas®- Bioglass® Bone Graft Particulate
Common Name : Synthetic Bone Grafting Material
Classification Name and No.: Bone Implant, Endosseous for Bone Filling and/or Augmentation 76LYC
Device Classification : Class III
Federal Register, Vol. 52, No. 155, Wednesday August 12, 1987, Section 872.3640, Docket Number 78N-2887.

Perioglas®-Bioglass® Bone Graft Particulate is a bioactive glass particulate (90-710 microns). Perioglas® has previously been shown to be substantially equivalent to a number of hydroxyapatite materials currently marketed, including Hapset™, Osteogen®, and Periograf® synthetic bone grafting materials. This equivalency was determined in Premarket Notification [510(k)] Number K930115, November 1993, in which Perioglas® is indicated for use in infraboney pockets caused by periodontal disease.

The intended uses have been extended to extraction sites and ridge augmentation based upon additional clinical data and determination of substantial equivalence to the legally marketed device Orthovita- Biogran™ (Ref. [510(k)]# K952922, K941780).

To confirm safety and efficacy, a recently completed human clinical study in extraction sites demonstrated favorable results for Perioglas® which documented significant new trabecular bone growth at two months after implantation. In this clinical study 16 patients and 20 sites were treated. At eight (8) weeks, radiographic analysis indicated that the Perioglas® integrated well into the bone tissue and by palpitation of the surgical sites, bone was pronounced solid. At six (6) months radiographic differences between the glass particles and bone tissue had nearly disappeared. Healing was uneventful without complaints from subjects. Two years follow-up demonstrated that Perioglas® is an effective osseous grafting material for the prevention of alveolar bone collapse restoration in extraction sites.

Physicians conclude that Perioglas® is both safe and effective in extraction sites and in reconstruction and augmentation of the alveolar ridge. Positive long-term results are expected, consistent with those documented for many years in the refereed literature in medicine and biomaterials.

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