K960353

510(k) SUMMARY

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January 22, 1996

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. Submitter:
   CeraMed Corporation
   12860 West Cedar Drive
   Lakewood, CO 80228
   (303) 985-0800

2. Device Name:
   OsteoGraf/LD-300 Hydroxylapatite
   Classification Name: Endosseous implant for bone filling and/or augmentation

3. Predicate Device:
   OsteoGraf/D-700 (previously OsteoGraf/AR) and others

4. Device Description:
   OsteoGraf/LD-300 is a high purity, radiopaque, polycrystalline form of hydroxylapatite, the major mineral phase of bone and dental enamel. It is manufactured as rounded, irregular shaped synthetic hydroxylapatite particles, sized at 250-420 microns.

5. Intended Use:
   The intended use of OsteoGraf/LD-300 is for the filling of periodontal defects and augmentation of bony defects of the alveolar ridge, including tooth extraction sites.

6. Comparison of Product Characteristics:
   OsteoGraf/LD-300 consists of 100% anorganic hydroxylapatite, $Ca_{10}(PO_4)_6OH_2$.

   X-ray diffraction and infrared analysis (FTIR) show OsteoGraf/LD-300 to be 100% hydroxylapatite. OsteoGraf/LD-300 conforms to the requirements of ASTM standard #F1185, "Composition of Ceramic Hydroxylapatite for Surgical Implants."