

510(k) SUMMARY

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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/N-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/N-300 is a natural, high purity, radiopaque, polycrystalline form of hydroxylapatite, the major mineral phase of bone and dental enamel. It is manufactured as anorganic, rounded, irregular shaped bovine derived hydroxylapatite particles, sized at 250-420 microns.
5. Intended Use:
The intended use of OsteoGraf/N-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/N-300 consists of 100% anorganic hydroxylapatite, $\text{Ca}_{10}(\text{PO}_4)_6\text{OH}_2$.

X-ray diffraction and infrared analysis (FTIR) show OsteoGraf/N-300 to be 100% hydroxylapatite. OsteoGraf/N-300 conforms to the requirements of ASTM standard #F1581, "Composition of Anorganic Bone for Surgical Implants."