

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
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Lakewood, CO 80228
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Contact Person: Barbara A. Watson
2. Device Name:
PermaMesh-D Hydroxylapatite Matrix, 1000 microns
Classification Name: Endosseous implant for bone filling and/or augmentation
3. Predicate Device:
PermaRidge
PermaMesh
4. Device Description:
PermaMesh-D is a synthetic form of hydroxylapatite, the major mineral component of tooth enamel and bone, produced in the form of a woven sheet. It is manufactured as high purity, radiopaque, rounded particles sized at 1000 microns diameter and organized into a flat, flexible clothlike form by means of absorbable suture.
5. Intended Use:
Bone filling and/or augmentation of the alveolar ridge.
6. Comparison of Product Characteristics:
PermaMesh-D consists of 100% synthetic hydroxylapatite beads strung on absorbable suture.

X-ray diffraction shows PermaMesh-D beads to be 100% HA. The hydroxylapatite component of PermaMesh-D conforms to ASTM Standard # F1185, "Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants", for trace elements. Typical calcium to phosphorus mole ratio is 1.68.