K960354
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510(k) SUMMARY

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
Contact Person: Barbara A. Watson

2. Device Name:

PermaMesh-D Hydroxylapatite Matrix, 1000 microns
Classification Name: Malar implant

3. Predicate Device:

MEDPOR® Surgical Implant

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:

Facial (malar) restoration and augmentation.

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 1.69.