K960349

1 of 1

MAR 13 1996

510(k) SUMMARY

January 22, 1996

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:
PermaRidge Hydroxylapatite Matrix, 1000 microns
Classification Name: Chin implant

3. Predicate Device:
MEDPOR® Surgical Implant
OsteoGraf/D-700 (Originally OsteoGraf/AR)

4. Device Description:
PermaRidge 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 restoration and augmentation.

6. Comparison of Product Characteristics:
PermaRidge consists of 100% synthetic hydroxylapatite beads strung on absorbable suture.

X-ray diffraction shows PermaRidge beads to be 100% HA. The hydroxylapatite component of PermaRidge 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.