K960362

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510(k) SUMMARY MAR 20 1996

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:
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2. Device Name:
PermaMesh Hydroxylapatite Matrix, 1000 microns
Classification Name: Malar implant

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

4. Device Description:
PermaMesh 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:
PermaMesh consists of 100% synthetic hydroxylapatite beads strung on absorbable suture.

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