

K962786

AUG - 1 1996 510(k) SUMMARY

July 15, 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
2. Device Name:  
OsteoGraf stainless steel syringe  
Classification Name: Syringe for Restorative and Impression Material
3. Predicate Device:  
OsteoGraf glass syringe  
Bio-Interfaces syringe
4. Device Description:  
The OsteoGraf stainless steel syringe is a device used for the delivery of restorative and impression material. It is composed of a stainless steel barrel, polypropylene plunger, and rubber plunger tip.
5. Intended Use:  
Delivery of restorative and impression material.
6. Comparison of Product Characteristics:  
The OsteoGraf stainless steel syringe consists of a stainless steel barrel, polypropylene plunger, and rubber plunger tip.