

SEP 10 1996

K963078

Steri-Oss Temporary Implant Cement  
Original 510(k) Submission

Section 6

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.  
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Yorba Linda, CA 92887  
U.S.A.  
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Regulatory Affairs  
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Date Prepared: August 1996

Devices Names:

Common Name: Dental Cement  
Trade Name: Steri-Oss Temporary Implant Cement  
Classification Name: Dental Cement

Predicate Device:

Substantial equivalence is claimed to Septodont's Resiment resin cement.

Device Description:

How the device functions: The Steri-Oss Temporary Implant Cement serves as a cement for retention of implant prosthesis. The cement is a two part paste which is self cured on mixing and application. The product is provided in two 10 gram containers of polyalkylene material.

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Intended Use:

The cement is indicated for use in the cementing (luting) of a implant prosthesis.

Comparison to Predicate

The following table provides a comparison of the technological characteristic of the Steri-Oss Temporary Implant Cement to the predicate.

Item	Predicate	Steri-Oss
Curing	Self Cured	Self Cured
System	Two part system	Two part system
Cement base	Resin filled	Resin filled

Performance Data

Not applicable, 510(k) requests a indication.