



K 960398

Original 510(k)  
Steri-Oss Apical Implant

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Section 7

letterhead

AUG -1 1996

510(k) Summary

**Manufacturer Information:**

Submitter's Name: Steri-Oss  
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Yorba Linda, CA 92687  
U.S.A.  
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Date Prepared: January 1996

**Device Names:**

Common Name: Endosseous dental implant  
Trade Name: Steri-Oss Apical Implant  
Classification Name: Endosseous implant

**Predicate Device:**

Substantial equivalence is claimed to Steri-Oss' Titanium Screw Series Implants.

**Device Description:**

How device functions: The Steri-Oss implant functions by serving as a replacement for the root portion of natural dentition, upon which a prosthetic may be constructed.

**Device Description (cont.):**

Scientific concepts: Natural dentition is composed of a root (subgingival) and a crown (supragingival). Designs in existence are intended to mimic this structure to aid the patient in restoring natural masticatory function. The implant is designed to serve as the root of the artificial tooth and the abutment/prosthetic is designed to serve as the crown.

Characteristics: The implant is threaded with a 3.8 mm width and an 8, 10, 12, 14, 16 and 18 mm length. The superior aspect is flat. Half of the implant is coated with hydroxylapatite.

**Intended Use:**

The implant is indicated for use in the mandible and maxilla for use as an artificial root structure for abutments for bridgework and denture retention.

**Comparison to Predicate:**

The following table provides a comparison of the technological characteristics of the Steri-Oss implant to the predicate.

Item	Predicate	Apical Implant
Material	Titanium alloy	Titanium alloy and HA
Coating Configuration	All but 1 mm neck (8 mm length)	50% of apical threads
	All but 2 mm neck (10, 12, 14, 16, 18 mm lengths)	
Width (mm)	3.8	Same
Length (mm)	8, 10, 12, 14, 16, 18	Same
Design	Threaded root form with flat superior aspect	Same
Packaging	Double vial	Same
Sterility	Sterile	Same

**Performance Data:**

Static tensile, static 90° transverse, static 30° compression and 30° compression fatigue were conducted on the predicate.