



Original 510(k)  
TPS Apical Implant

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Section 6

510(k) Summary

**Manufacturer Information:**

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

**Device Names:**

Common Name: Endosseous dental implant  
Trade Name: TPS Apical Implant  
Classification Name: Endosseous implant

**Predicate Device:**

Substantial equivalence is claimed to Steri-Oss' Apical 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 titanium.

**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	TPS Apical Implant
Material	Titanium and HA	Titanium
Width (mm)	3.8	Same
Length (mm)	8 - 18	Same
Geometry	Threaded	Same
Sterility	Sterile	Same

**Performance Data:**

Not applicable.