

K964220

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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Date Prepared: October 1996

**Device Names:**

Common Name: Implant  
Trade Name: Replace Titanium Implant System  
Classification Name: Endosseous implant

**Predicate Device:**

Substantial equivalence is claimed to Steri-Oss Titanium Implants, Healing Screws, Healing Abutments and Abutments.

**Device Description:**

How device functions: The Steri-Oss Replace Titanium Implant System is designed to serve as support for prosthetic devices to restore patient chewing function.

**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 implants are 4.3, 5.0 or 6.0 mm in diameter, from 10 - 16 mm in length and are composed of titanium. They are tapered, threaded and have a hexed superior surface. The Replace Titanium Implant System utilizes color coding.

**Intended Use:**

The implant is indicated for use in restoring masticatory function in the edentulous and/or partially edentulous patient.

**Comparison to Predicate:**

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

Item	Predicate	Steri-Oss
Material	Titanium	Same
Surface characteristics	Non-color coded	Color coded
Sterility	Sterile	Same

**Performance Data:**

Not applicable.