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K960886

Section 6

letterhead

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss

Address: 22895 Eastpark Drive
Yorba Linda, CA 92687
U.S.A.

Contact's Name: Paul Gasser
Regulatory Affairs Specialist

Phone: 714-282-4800

Date Prepared: February 1996

Device Names:

Common Name: Implant

Trade Name: None

Classification Name: Endosseous implant

Predicate Device:

Substantial equivalence is claimed to Nobelpharma's 3.75 mm implant.

Device Description:

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

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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 6 mm in diameter, from 8 - 18 mm in length and are composed of titanium and hydroxyl-apatite (HA). They are available with a flat or hex lock superior surface, and are either cylindrical or threaded.

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	Titanium and HA
Diameter (mm)	3.75	6
Length (mm)	7 - 20	8 - 18
Geometry	Threaded	Threaded or Cylindrical
Sterility	Sterile	Same

Performance Data:

A mathematical justification demonstrates the substantial equivalence of the predicate to the Steri-Oss products.