

NOV 26 1997

Original 510(k)  
Steri-Oss 3.25 mm Replace Dental Implant System

Section 6

K973402

**510(k) Summary**

**Manufacturer Information:**

Submitter's Name: Steri-Oss Inc.  
Submitter's Address: 22895 Eastpark Drive  
Yorba Linda, CA 92887  
USA  
Contact's Name: Jeff Hausheer, Ph.D.  
Contact's Telephone: 714-282-4800, extension 3815  
Date Prepared: September 1997

**Device Name:**

Common Name: Prosthetic Dental Implant System  
Trade Name: Steri-Oss 3.25 mm Replace Dental Implant System  
Classification Name: Endosseous dental implant

**Predicate Device:**

Substantial equivalence is claimed to Steri-Oss' Replace Implants, Healing Screws, Healing Abutments, and Abutments (K964220) and to Steri-Oss' (3.25 mm diameter) Titanium Plasma Sprayed Cylindrical Implant (K911592).

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**510(k) Summary**

**Device Description:**

**How The Device Functions:**

Individual components fulfill the following purposes:

**Steri-Oss 3.25 mm Replace Implant:** This device is designed to serve as support for prosthetic devices to restore patient chewing function.

**Steri-Oss 3.25 mm Replace Healing Screw:** This device is designed to protect the internal threads of the implant during healing.

**Steri-Oss 3.25 mm Replace Healing Abutment:** This device is designed to expand the gingival tissue during the healing phase to maintain the appropriate abutment fit.

**Steri-Oss 3.25 mm Replace Abutment:** This device is designed to serve as a base for prosthetic devices which restore patient chewing function.

**Scientific Concepts:**

Natural dentition is composed of a root (subgingival) and a crown (supragingival). Endosseous dental implant designs in existence are intended to mimic this structure to aid the patient in restoring natural masticatory function. The subject implant is designed to serve as the root of the artificial tooth and the abutment/prosthesis is designed to serve as the crown. The healing screw and healing abutment are intermediary devices which serve to permit satisfactory completion of the implant healing/restoration process.

**Device Characteristics:**

The implants are 3.25 mm in diameter, are 10 to 16 mm in length, and are fabricated from titanium alloy. They are tapered, threaded, and have a superior external hex. The healing screw, healing abutment, and abutment are also fabricated from titanium alloy. Portions of the surface of each of the components are anodized magenta in color.

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**510(k) Summary**

**Intended Use:**

The intended use for this device system is to serve as support for prosthetic devices to restore patient chewing functions.

**Comparison to Predicate:**

The following table provides a comparison of the principle technological characteristics of the 3.25mm Replace Implant System and the predicate.

**Comparison to Predicates:**

Specification/ Characteristic	Predicate: Steri-Oss Replace Implant	New Product: Steri-Oss 3.25 mm Replace Dental Implant
Material	Titanium	Same
Surface Characteristics	Color-coded	Same
Sterility	Sterile	Sterile

**Performance Data:**

Not applicable.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 26 1997

Jeff Hausheer, Ph.D.  
Regulatory Affairs Specialist  
Steri-Oss, Incorporated  
22895 East Park Drive  
Yorba Linda, California 92687

Re: K973402  
Trade Name: Steri-Oss 3.25mm Replace Dental Implant  
System  
Regulatory Class: III  
Product Code: DZE  
Dated: September 8, 1997  
Received: September 9, 1997

Dear Dr. Hausheer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

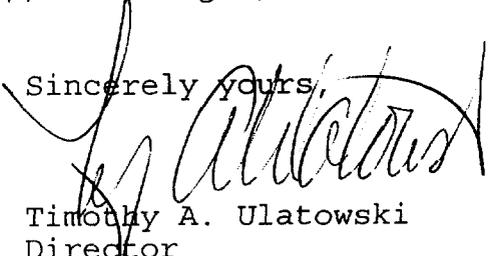
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Original 510(k)  
Steri-Oss 3.25 mm Replace Dental Implant System

Section 9

Indications for Use

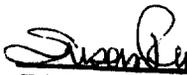
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510(k) Number (if known):     K973402    

Device Name:           3.25 mm Replace Dental Implant System

Indications For Use: The intended use for this device is to serve as support for prosthetic devices to restore patient chewing function.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number     K973402    

Prescription Use            OR Over-The-Counter Use  (Per 21 CFR 801.109)

(Optional Format 1-2-96)