



K980439

Original 510(k)
Replace Cylindrical Implants

MAR 16 1998

39

Section 6

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.
 Address: 22895 Eastpark Drive
 Yorba Linda, CA 92887
 U.S.A.
 Contact's Name: Paul Gasser
 Manager, Regulatory Affairs/
 Quality Assurance
 Phone: 714-282-4800
 Date Prepared: January 1998

Device Names:

Common Name: Endosseous Dental Implant
 Trade Name: Replace Cylindrical Implant
 Classification Name: Endosseous implant

Predicate Device:

Substantial equivalence is claimed to Steri-Oss Replace Titanium Implants.

Device Description:

How device functions: The Steri-Oss Replace Cylindrical Implant 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 3.25, 4.3, 5.0 or 6.0 mm in diameter, from 10 - 16 mm in length and are composed of titanium. They are tapered, cylindrical and have a hexed superior surface. The implants may be non-coated or coated (HA or TPS). The Replace Cylindrical Implants utilize 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 without coating or coated (HA or TPS)	Same
Geometry	Threaded	Cylindrical
Surface characteristics	Color coded	Same
Sterility	Sterile	Same

Performance Data:

Not applicable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1998

Mr. Paul Gasser
Manager, Regulatory Affairs/Quality Assurance
Steri-Oss®, Incorporated
22895 Eastpark Drive
Yorba Linda, California 92887

Re: K980439
Trade Name: Replace Cylindrical Implants
Regulatory Class: III
Product Code: DZE
Dated: February 3, 1998
Received: February 4, 1998

Dear Mr. Gasser:

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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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) 594-4692. 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

Section 9

Indications for Use

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510(k) Number (if known): K980439

Device Name: Replace Cylindrical Implant

Indications For Use:

The intended use for these devices 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)

Shawn Runier
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K980439

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)