K972965

Steri-Oss Until Implant Cement
Orginal 510(k) Submission

NOV - 7 1997

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:	Don Kennard Regulatory Affairs
Phone:	714-282-4811
Fax:	714-988-9236
Date Prepared:	August 1997

Devices Names:

Common Name:	Dental Cement
Trade Name:	Steri-Oss Until Implant Cement
Classification Name:	Dental Cement

Predicate Device:

Substantial equivalence is claimed to Steri-Oss Temporary cement.

Device Description:

How the device functions: The Steri-Oss Until Implant Cement serves as a cement for retention of implant prosthesis. The cement is a two part paste that is self cured on mixing and application. The product is provided in two 10 gram containers of polyalkylene material.

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Intended Use:

The cement is indicated for use in the cementing (luting) of a implant prosthesis.

Comparison to Predicate

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

Item	Predicate (Steri-Oss Temporary)	Steri-Oss (Until)
Curing	Self Cured	Self Cured
System	Two part system	Two part system
Cement base	Resin filled	Resin filled

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Don Kennard
Regulatory Affairs
Steri-Oss, Incorporated
22895 East Park Drive
Yorba Linda, California 92687

NOV - 7 1997

Re: K972965
Trade Name: Steri-Oss Until Implant Cement
Regulatory Class: II
Product Code: EMA
Dated: August 8, 1997
Received: August 11, 1997

Dear Mr. Kennard:

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

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Section 7

Indications for use

510(k) Number K972965

Device Name: Steri-Oss Until Implant Cement

Indications for Use:

Steri-Oss Until Implant Cement is indicated for cementing (luting) of a implant prosthesis.

(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 K972965

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the Counter Use____

(Optional Format 1-2-96)