

SEP 23 1998

K982400

Steri-Oss' ImProv Temporary Dental Cement
Original 510(k) Submission

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:	Jeff Hausheer, Ph.D. Regulatory Affairs Specialist
Phone:	714-282-4800
Fax:	714-988-9236
Date Prepared:	July 1998
Device Name:	
Common Name:	Crown and Bridge Cement
Trade Name:	Steri-Oss' ImProv Temporary Dental Cement
Classification Name:	Dental Cement

Predicate Device:

Substantial equivalence is claimed to Steri-Oss' Until Implant Cement (510(k) K972965), cleared on November 7, 1997, and intended for cementation (luting) of an implant prosthesis, and to Scientific Pharmaceutical's Interim Cement (510k) K884081, cleared on December 2, 1988, and intended for cementation (luting) of crown and bridge prostheses to natural tooth abutments .

Section 6 (continued)

510(k) Summary

Device Description:

How the device functions:

Steri-Oss' ImProv Temporary Dental Cement serves as a cement for the temporary retention of crown and bridge prostheses. The cement is an anaerobic two part paste which self-cures upon mixing. The product is provided in two syringe-like cylinders made of a polyalkylene material, one containing 10 grams of cement Part A and one containing 10 grams of cement Part B.

Intended Use:

Steri-Oss' ImProv Temporary Dental Cement is intended for cementing (luting) of crown and bridge prostheses to natural tooth abutments.

Comparison to Predicate

The following table provides a comparison of the technological characteristics of Steri-Oss' ImProv Temporary Dental Cement to the predicate devices.

Characteristic	Predicate 1: Interim Cement	Predicate 2: Until Implant Cement	New Product: ImProv
Curing	Anaerobic Self-curing	Anaerobic Self-curing	Same
System	Two part system	Two part system	Same
Cement Base	Resin filled	Resin filled	Same

Performance Data

Not applicable



SEP 23 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jeff Hausheer, Ph.D.
Regulatory Affairs Specialist
Steri-Oss, Incorporated
22895 Eastpark Drive
Yorba Linda, California 92887

Re: K982400
Trade Name: Steri-Oss' ImProv Temporary Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: July 10, 1998
Received: July 10, 1998

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.

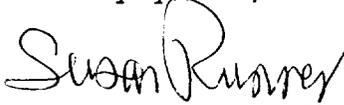
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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) 594-4692. 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,


For 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 8

Indications for Use

Page 1 of 1

510(k) Number (if known): _____

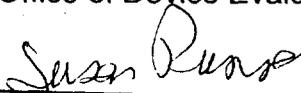
Device Name: Steri-Oss' ImProv Temporary Dental Cement

Indications For Use:

Steri-Oss' ImProv Temporary Dental Cement is intended for cementing (luting) of crown and bridge prostheses to natural tooth abutments.

(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 1K980400

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

(Optional Format 1-2-96)