

OCT - 9 1998

K982895
510(k) Summary

Trade Name: SternOmega Dental Compomer Cement Automix

Sponsor: Sterngold ImplaMed
23 Frank Mossberg Drive
P.O. Box 2967
Attleboro, MA 02703-0967
Registration #2921595

Device Generic Name: Dental bonding agent

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices: The proposed SternOmega Compomer Cement is substantially equivalent to a number of currently marketed dental cements and bonding agents including the following:

<u>Product/510(k) #</u>	<u>Manufacturer</u>
Optibond/K940513	Kerr
Panavia 21/K933030	Kuraray/J. Morita
C&B Luting Composite/K940030	Bisco
Flexi-Flow/K922249	EDS
C&B Metabond/K960464	Parkell
Duolink/K943596	Bisco
Variolink/931309	Vivadent
Advance/K940914	Dentsply
Dyract Cem/Unknown	Dentsply
Fuji Duet (Fuji Plus)/K946100	GC
Resinomer/K924151	Bisco
Cement-It/Unknown	Jeneric/Pentron
ABC Dual Adhesive Bridge Cement/ Unknown	Vivadent

Product Description:

The SternOmega Dental Compomer Cement is an auto-mixing, chemical cure, radiopaque cement indicated for the permanent luting of crowns, bridges, inlays and onlays. The cement contains fluoride which is released over time to provide the benefits associated with a fluoride-releasing material.

Indications for Use:

The SternOmega Compomer Cement is indicated for permanent luting of crowns, bridges, inlays and onlays and for luting ceramic crowns, inlays and veneers.

Safety and Performance:

Substantial equivalence for this device was based solely on design and performance characteristics; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the Compomer Cement are equivalent to those of the predicate devices.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the SternOmega Dental Compomer Cement has been shown to be safe and effective for its intended use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sterngold Implamed
C/O Ms. Pamela Papineau
Delphi Medical Device Consultant
50 Brewster Street
Pawtucket, Rhode Island 02860

Re: K982895
Trade Name: Sternomega Compomer Cement
Regulatory Class: II
Product Code: EMA
Dated: August 14, 1998
Received: August 17, 1998

Dear Ms. Papineau:

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.

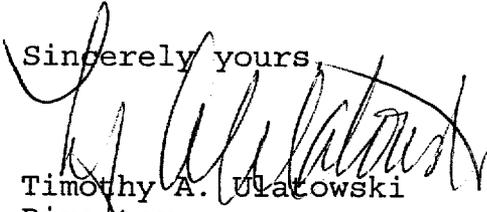
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Papineau

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

510(k) Number (if known): K982895

Device Name: SternOmega Compomer Cement Automix

Indications for Use:

SternOmega Compomer Cement Automix is indicated for use in permanent luting of crowns, bridges, inlays and onlays and for luting ceramic crowns, inlays and veneers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Purse

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

510(k) Number K982895

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use