

OCT 22 1998

510(k) Summary

K 982692

Trade Name: SternOmega Dental Composite System consisting of SternOmega Bonding Agent, SternOmega Composite LC and SternOmega Compomer LC

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

Device Generic Name: Dental composite system

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

Predicate Devices:

Product Name	510(k) #	Manufacturer
SternOmega Bonding Agent		
Prime & Bond 2.1	K962348	Dentsply Int'l.
Optibond Solo Single Component	K940513	Kerr Mfg. Co.
Dentemp One Step	K964773	Bisco (Majestic Drug Co.)
Bond I	K973388	Jeneric/Pentron Inc.
Single Bond	Unknown	3M
SternOmega Composite LC		
XRV Herculite	K844662	Kerr Mfg. Co.
Prodigy AC	K963805	Sybron Dental Specialties
Renamel Hybrid	K921820	Cosmedent, Inc.
Charisma	K932013	Heraeus Kulzer
Tetric Ceram	K964285	Ivoclar North America
Tetric	K922569	Ivoclar North America
SternOmega Compomer LC		
Compoglass	K951836	Ivoclar North America
Dyract	K950991	Dentsply Int'l.
Hytac Aplitip	K962442	ESPE

Product Description:

The SternOmega Bonding Agent is a light-curing, one-component bonding agent for compomer and composite, which is applied to dentin and enamel. The bonding agent is self-conditioning, having the primer and bonding adhesive in one bottle.

The SternOmega Composite LC is a single-paste, light-curing, radiopaque universal hybrid composite dental filling material indicated for filling all classes of cavities. It is used in conjunction with the SternOmega Bonding Agent.

The SternOmega Compomer LC is a single-paste, light-curing, radiopaque dental filling material indicated for permanent filling of Class III and V cavities, and for temporary filing of Class I and II cavities. It is used in conjunction with the SternOmega Bonding Agent.

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Indications for Use:

The SternOmega Dental Composite System is indicated for dental filling of cavities.

The SternOmega Composite LC is indicated for filling of all classes of cavities.

The SternOmega Compomer LC is indicated for Class V restorations, cervical abrasions and erosions, Class III restorations, and for restorations of all cavity classes including Classes I and II in deciduous teeth.

The SternOmega Bonding Agent is indicated for all adhesive restorations with compomers and composites, including the SternOmega Composite LC and the SternOmega Compomer LC.

Safety and Performance:

This submission is a Special 510(k): Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Sterngold Implamed has provided information to demonstrate conformity with FDA's guidance document entitled *Guidance for the Preparation of a Premarket Notification (510(k)) for Direct Filling Dental Composites*, January 1996.

Conclusion:

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1998

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

Re: K982692
Trade Name: SternOmega Bonding Agent, SternOmega
Composite LC, SternOmega Compomer LC
Regulatory Class: II
Product Code: EBF
Dated: July 27, 1998
Received: August 3, 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.

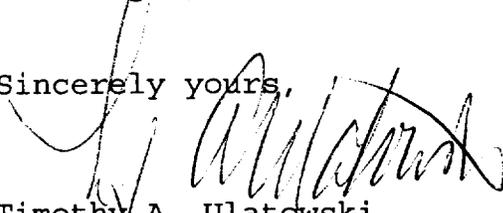
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Device Name: SternOmega Dental Composite System consisting of :
SternOmega Bonding Agent, SternOmega Composite LC and SternOmega
Compomer LC

Indications for Use:

The SternOmega Dental Composite System is indicated for dental filling of cavities.

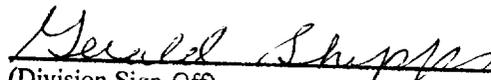
The SternOmega Composite LC is indicated for filling of all classes of cavities.

The SternOmega Compomer LC is indicated for Class V restorations, cervical abrasions and erosions, Class III restorations, and for restorations of all cavity classes including Classes I and II in deciduous teeth.

The SternOmega Bonding Agent is indicated for all adhesive restorations with compomers and composites, including the SternOmega Composite LC and the SternOmega Compomer LC.

(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 K982692

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

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