K984340

JAN 8 1999

510(k) Summary

Trade Name: **SternOmega Dental Temporary Cement Automix NE**

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 Device: The proposed SternOmega Temporary Cement Automix NE is substantially equivalent to the TempoCem NE temporary dental cement marketed by Foremost Dental Manufacturing, Inc. which was cleared for marketing by FDA in K970774.

Product Description:
The SternOmega Temporary Cement Automix NE is an auto-mixing, non-eugenol cement indicated for the temporary bonding of crowns, bridges and inlays.

Indications for Use:
SternOmega Temporary Cement Automix NE is indicated for use as a temporary cement for attaching all types of temporaries, e.g. temporary crowns, bridges, and inlays.

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 Temporary Cement Automix NE are equivalent to those of the predicate device.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate device, the SternOmega Temporary Cement Automix NE has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 1999

Mr. Gordon Nelson
Director
Sterngold ImplaMed
23 Frank Mossberg Drive
P.O. Box 2967
Attleboro, Massachusetts 02703-0967

Re: K984340
Trade Name: SternOmega Temporary Cement Automix NE Model 220282/220281
Regulatory Class: II
Product Code: EMA
Dated: December 2, 1998
Received: December 4, 1998

Dear Mr. Nelson:

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 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,

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): K984340

Device Name: SternOmega Temporary Cement Automix NE

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984340