JAN 8 1999

K984341

510(k) Summary

Trade Name: **SternVantage Varnish LC**

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

Device Generic Name: Denture relining, repairing and rebasing resin

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

Predicate Devices: The proposed SternVantage LC is substantially equivalent to the Palaseal material marketed by Kulzer, Inc. which was cleared for marketing by FDA in K892452.

Product Description:
The SternVantage Varnish LC material is a single-component, acrylate-based, light-curing surface coating material for dental applications.

Indications for Use:
SternVantage Varnish LC is a surface sealing and finishing material for use on polymerized composite surfaces, denture bases, and temporary crowns and bridges.

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 Varnish LC are equivalent to those of the predicate device.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the SternVantage Varnish LC 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: K984341
Trade Name: SternVantage Varnish LC, Model 221001
Regulatory Class: II
Product Code: EBI
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): K984341

Device Name: SternVantage Varnish LC

Indications for Use:

SternVantage Varnish LC is a surface sealing and finishing material for use on polymerized composite surfaces, denture bases, and temporary crowns and bridges.

(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 K984341