

SS WHITE

K972935

JAN 29, 1998

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PREMARKET NOTIFICATION

510 (k) SUMMARY

NAME: S.S. White Manufacturing

ADDRESS: Unit 9, Madleaze Estate,
Bristol Road,
Gloucester,
GL1 5SG
England

PHONE No: 01452 307171

FAX No.: 01452 307187

CONTACT: Hugh Savell
SS White Group Compliance Manager

DATE PREPARED: 4th August, 1997

PREMARKET NOTIFICATION**510(k) SUMMARY (continued)**

TRADE NAME: Super-Dent Intermediate Restorative Material

COMMON NAME: Temporary Dental Cement

CLASSIFICATION NAME: Cement, Dental

EQUIVALENT TO: Temporary Dental Cement; 510(k) number K895487,

DESCRIPTION:

These materials consist of a powder and liquid which, when mixed together, form a setting mass suitable for their intended use.

INTENDED USE:

These materials are intended for use in dentistry as a base or cavity liner under permanent restorations and for temporary restorations to teeth.

TECHNOLOGICAL CHARACTERISTICS:

These materials rely on the reaction between zinc oxide and eugenol (4-Allyl-2-methoxyphenol) to form a setting mass. They are chemically modified to control the setting reaction and are reenforced with polymers to give enhanced strength and a surface more resistant to abrasion.

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PREMARKET NOTIFICATION**510(k) SUMMARY (continued)****NON-CLINICAL DATA:**

The setting characteristics of these materials are essentially identical at the stipulated mixing ratios. The compressive strength of the subject device is slightly lower and the disintegration slightly higher than the predicate device.

The subject device is subjectively very much easier to mix which is an important advantage in surgery use.

CLINICAL DATA:

There is none applicable.

CONCLUSIONS:

The data summarised above indicates that the subject device is substantially equivalent to the predicate device.

The slightly lower performance of the subject device is considered to be out-weighed by its easier mixing. This ensures a consistently homogenous mix and thereby more reliable performance in clinical use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Hugh Savell
Technical and Compliance Manager
S.S. White Manufacturing, Ltd.
9 Madleaze Estate, Bristol Road
Gloucester,
G11 5SG. England

Re: K972935
Trade Name: Super-Dent Intermediate Restorative Material
Regulatory Class: II
Product Code: EMA
Dated: December 16, 1997
Received: December 22, 1997

Dear Mr. Savell:

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.

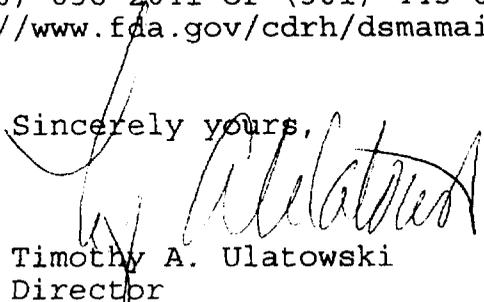
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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): K 972935

Device Name: SUPER-DENT INTERMEDIATE RESTORATIVE

Indications For Use: MATERIAL

This material is intended for use in dentistry as a base or cavity liner under permanent restorations and for temporary restorations to teeth as an interim measure to protect cavities before a permanent restoration can be completed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rumpf
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972935

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)