JUN - 3 2004

K040994

510(k) SUMMARY
As required by the Safe Medical Devices Act of 1990

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICES

Den-Mat Core Paste
Bisco Bis-Core
Bisco Bisfil Core

The three predicate devices are highly filled resin restorative materials designed to serve as core buildup materials to restore the structural portion of a tooth crown. The built-up structure is intended to be restored with a fixed dental prosthesis such as a crown.

These products are fabricated from bis-GMA, urethane, or similar room temperature curing diacrylate monomers that are filled with silanated silica and/or glasses typically formulated with metal oxides which are sufficiently radioapparent as to be visible on clinical radiographs.

DESCRIPTION OF THE APPLICANT DEVICE – CORE PASTE

CORE PASTE is a dual-cure, radiopaque, filled, resin based core buildup material. The product will self-cure upon mixing equal parts of base and catalyst pastes. The setting time and resultant properties can be improved by further curing with a visible light dental curing unit.

CORE PASTE is a high strength product ideally suited to buildup or replace lost tooth structure and to perform as a foundation restoration or core. It is used to build a damaged tooth to ideal anatomic form before it is prepared for a fixed dental prosthesis such as a crown.

CORE PASTE is available in three shades: a blue material which serves to sharply contrast with tooth structure, a white opaque shade with similar clinical effects, and an esthetic A2 shade for optimal optical effects under esthetic translucent crown materials.

INTENDED USES OF THE APPLICANT DEVICE

CORE PASTE is a dental core buildup material intended to be used with 4th or 5th generation resin adhesive primer/bonding systems.

James L. Sandrik, PhD

Cosmedent, Inc.
401 N. Michigan Avenue
Suite 2500
Chicago, Illinois 60611
Submitted: April 14, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2004

James L. Sandrik, PhD
Director of Regulatory Affairs
Cosmedent, Incorporated
401 North Michigan Avenue, Suite 2500
Chicago, Illinois 606011

Re: K040994
Trade/Device Name: Core Paste™
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 15, 2004
Received: April 16, 2004

Dear Dr. Sandrik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

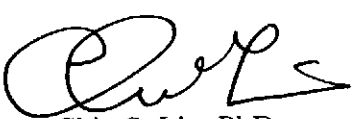
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K040994

Device Name: MULTIPLE (**CORE PASTE**)

Indication For Use:

• Dental core buildup material for use with 4th or 5th generation resin adhesive primer/bonding systems.

Prescription Use___X____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

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