K042804

FEB - 1 2005



# Section 5
# 510 (k) SUMMARY

Applicant: Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193

Contact Person: Benjamin Lichtenwalner
Tel: 847-534-6146
Fax: 847-534-6111

Date Prepared: October 8, 2004

Trade Name: **TESCERA Opaquer/Sculpting Resin and Opaquer Powder**
Common Name: Dental Opaquing/Masking Composite and Wetting Resin
Classification/Name: Tooth Shade Resin Material
**Class II per 21 CFR 872.3690**

**Description of Applicant Device:**

**TESCERA Opaquer/Sculpting Resin** is a dual-cured (light/heat), low viscosity resin for used for wetting composite instruments. With **TESCERA Opaquer Powder, TESCERA Opaquer/Sculpting Resin** is a dual-cured (light/heat) tooth colored opaquing/masking composite system specially formulated to opaque/mask the substrates used in dental restorations.

**Intended uses of Applicant Device:**

**TESCERA Opaquer/Sculpting Resin** is intended for wetting instruments to aid in the placement and shaping of composites. **TESCERA Opaquer/Sculpting Resin** mixed with **TESCERA Opaquer Powder** is a dual-cured (light and/or heat cured) tooth colored opaquing/masking composite system intended for masking the materials used in dental prostheses.

**TESCERA Opaquer Powder and Opaquer/Sculpting Resin** are optimized for use with the TESCERA ATL (Aqua-Thermal-Light) system.

**Predicate Devices**:

D/C OPAQUER (a.k.a. Opaquer Resin), cleared under Bisco Porcelain Repair Kit (K874557) dated January 28, 1988.

MODELING RESIN (a.k.a. Sculpting Resin), cleared under Sculpting Resin (K030585) dated May 2, 2003.

## Section 5
## 510 (k) SUMMARY (continued)

**Significant Performance Characteristics:**

### D/C OPAQUER to TESCERA Opaquer/Sculpting Resin and Opaquer Powder

| Property | D/C OPAQUER | TESCERA Opaquer/Sculpting Resin and Opaquer Powder |
|---|---|---|
| Intended use | Substrate Opaquer/Masker | Substrate Opaquer/Masker |
| Chemical composition | Dual cure (light and self), filled, dimethacrylate composite | Dual cure (heat and light), filled, dimethacrylate composite |
| Mechanical /physical properties | Low viscosity, tooth colored, paste-to-paste opaquer/masker | Low viscosity, tooth colored, powder-to-resin opaquer/masker |

### MODELING RESIN to TESCERA Opaquer/Sculpting Resin

| Property | MODELING RESIN | TESCERA Opaquer/Sculpting Resin |
|---|---|---|
| Intended use | Wetting of composite instruments | Wetting of composite instruments |
| Chemical composition | Light cured, filled, dimethacrylate composite | Dual cured (heat/light), unfilled, dimethacrylate resin |
| Mechanical /physical properties | Slightly viscous, straw colored, instrument wetting agent | Low viscosity, light yellow, instrument wetting agent |

Side by side comparisons of **TESCERA Opaquer/Sculpting Resin** and **Opaquer Powder** to the predicate devices **D/C OPAQUER and MODELING RESIN** clearly demonstrate that the applicant device is substantially equivalent to the legally marked devices. **TESCERA Opaquer/Sculpting Resin** and **Opaquer Powder** were tested for biocompatibility and they were found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **TESCERA Opaquer/Sculpting Resin and Opaquer Powder.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 W. Irving Park Road
Schaumburg, Illinois 60193

Re: K042804
Trade/Device Name: TESCERA Opaquer/Sculpting Resin and Opaquer Powder
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 22, 2004
Received: January 25, 2005

Dear Mr. Lichtenwalner:

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.

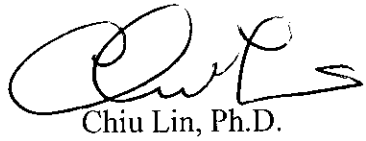
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,



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

Enclosure

510 (k) Number (if known): K042804

Device Name: TESCERA Opaquer/Sculpting Resin and Opaquer Powder

Indications for Use:

**TESCERA Opaquer/Sculpting Resin** is a pre-wetting agent for placing and sculpting layers of composites.

When mixed with **TESCERA Opaquer Powder, TESCERA Opaquer/Sculpting Resin** is a dual-cured material (light/heat) used to opaque/mask metal substrates and other materials used in dental restorations.

Prescription Use ✓ 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042804