

K060701

**Section 5
510 (k) SUMMARY**

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

Contact Person: Benjamin Lichtenwalner
 Tel: 847-534-6146
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Date Prepared: March 15, 2006

Trade Name: **BisCem**
 Common Name: Luting Cement
 Classification/Name: Material, Dental Cement
Class II per 21 CFR 872.3275

Description of Applicant Device:

BisCem is a dual-cured self etching and self adhesive resin cement. It is a self-adhesive cement since it bonds to composite, metal, silanated porcelain and tooth structure without applying any adhesive. No etching step is required to bond to dentin or enamel. With its dual syringe system, **BisCem** can be self cured by simply mixing paste **A** and paste **B** or cured by light after mixing paste **A** and paste **B**. Using a mixing tip, the cement could be dispensed to the working area directly. It is intended for use as a luting cement.

Intended uses of Applicant Device:

BisCem is a dual-cure radiopaque dental cement designed to be used as a luting cement. Its physical properties and uses are similar to the predicate device.

Predicate Devices: **BisCem GI** cleared under (K032597) dated November 4, 2003.

Significant Performance Characteristics:

	BisCem GI	BisCem
Intended use	Luting cement	Luting cement
Chemical composite	Dual-cured (self/light) dental glass filled, resin modified glass ionomer cement	Dual-cured (self/light) dental glass filled, resin cement
Mechanical /physical properties	Low viscosity, dispensable composite	Low viscosity, dispensable composite

Side by side comparisons of **BisCem** to the predicate device **BisCem GI** clearly demonstrates that the applicant device is substantially equivalent to the legally marked device. **BisCem** was tested for biocompatibility and it was found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **BisCem**.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2006

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

Re: K060701
Trade/Device Name: BisCem
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: May 02, 2006
Received: May 05, 2006

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.

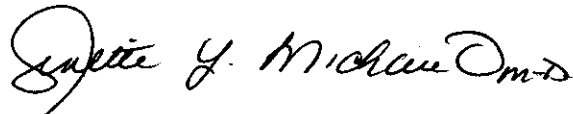
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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" (21 CFR 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 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

12060701

510 (k) Number (if known): _____

Device Name: BISCEM

Indications for Use:

1. Luting metal crowns, bridges, inlay, and onlays including porcelain-fused-to-metal and composite-to-metal varieties;
2. Luting resin crowns, bridges, inlays, onlays and veneers;
3. Luting metal or non-metal/fiber posts;
4. Luting orthodontic appliances;
5. Luting porcelain inlays, onlays, crowns, and veneers (includes alumina and zirconia).

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)



(Print Name)
Susan R. [unclear], Department of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: 12060701