K073263

Section 5
510 (k) SUMMARY

FEB 14 2008

Applicant: Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193
Contact Person: Benjamin Lichtenwainer
Tel: 847-534-6146
Fax: 847-534-6111
Date Prepared: November 19, 2007

Trade Name: **PRO-V**
Common Name: Temporary/Provisional Filling Material
Classification/Name: Dental Cement
Class II per 21 CFR 872.3275

Description of Applicant Device:

PRO-V is line of provisional restorative materials designed to address the differing requirements for creating or placing any provisional restoration. The **PRO-V System** consists of **PRO-V FLO, PRO-V FILL**, and **PRO-V COAT. PRO-V FLO™** is a flowable composite for use as a provisional for inlay restorations. **PRO-V FILL™** is a packable composite for use as a provisional for onlay restorations. **PRO-V COAT™** is a separating agent.

Intended uses of Applicant Device:

The **PRO-V COAT** is easily applied to an adhesive coated tooth surface before temporization with **PRO-V FLO** or **PRO-V FILL** for provisional inlay or onlay restorations. The **PRO-V COAT** provides a barrier between the applied adhesive resin and provisional filling materials. The **PRO-V FLO** or **PRO-V FILL** can then be easily removed when no longer needed and the **PRO-V COAT** is simply rinsed off with copious amounts of water.

Predicate Devices: **E-Z Temp** cleared under (K924132) dated July 8, 1993.

Significant Performance Characteristics:

SUBSTANTIAL EQUIVALENCE SUMMARY

	E-Z Temp	PRO-V
Intended use	Provisional Inlay and Onlay Restorative	Provisional Inlay and Onlay Restorative
Chemical composite	Light-cured, glass filled, resin based inlay and onlay composite supplied with a water-soluble separating agent	Light-cured, glass filled, resin based inlay and onlay composite supplied with a water-soluble separating agent
Mechanical / Physical properties	**E-Z Temp Inlay**: Low viscosity dispensable composite **E-Z Temp Onlay**: High viscosity sculptable composite **E-Z Temp Separating Agent**: Water-soluble separating agent	**PRO-V FLO:** Low viscosity, dispensable composite **PRO-V FILL**: High viscosity sculptable composite **PRO-V COAT**: Water-soluble separating agent

Side by side comparisons of **PRO-V** to the predicate device **E-Z Temp** clearly demonstrates that the applicant device is substantially equivalent to the legally marked device. **PRO-V** 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 **PRO-V**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

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

Re: K073263
Trade/Device Name: PRO-V
Regulation Number: 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: November 19, 2007
Received: November 20, 2007

Dear Mr. Benjamin 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.

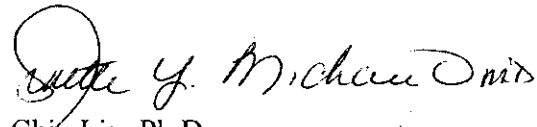
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K073263

Device Name: PRO-V

Indications for Use Statement:

PRO-V is line of provisional restorative materials designed to address the differing requirements for creating or placing any provisional restoration. The **PRO-V System** consists of **PRO-V FLO, PRO-V FILL,** and **PRO-V COAT** which offers a complete solution to create an effective inlay or onlay provisional.

Indications for Use:

A. Temporary fillings
B. Provisional Inlays
C. Provisional Onlays

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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