AUG 25 [illegible]

K992248

Attachment 5 – 510(k) Summary

1. Bisco, Inc.
   1100 W. Irving Park Road
   Schaumburg, IL 60193
   847-534-6000
   Contact: Kathryn B. Patterson, Regulatory Affairs Manager
   Date Prepared: July 2, 1999

2. Device Trade Name: Post Cement Hi-X
   Common/Usual Name: Dental Post Cement
   Classification Name: Dental Cement

3. Predicate Device: C & B Luting Cement, K940030 (cleared February 4, 1994)

4. Post Cement Hi-X Dental Cement is a self-cured, radiopaque composite and is designed to be used with Bisco's dental adhesive systems such as All-Bond® 2 or One-Step® Universal Adhesive Systems. Post Cement Hi-X will bond micro-mechanically to fiber posts, metal, silane-treated porcelain, fibers and tooth structure. Due to its high opacity in thin layers, Post Cement Hi-X is intended for cementation of posts. When viewed on x-ray film, the outline of any post material will be visible with the use of Post Cement Hi-X. Post Cement Hi-X, a low-viscosity, tooth-colored, silica and glass-filled, resin-based composite, is a two-paste, self-cured system. The material is supplied in syringes.

5. The intended use of Post Cement Hi-X is:
   - for the cementation of posts
   - for the cementation of metal posts fabricated with precious, semi-precious or non-precious metals

6. Post Cement Hi-X possesses the same technological characteristics as the predicate device, C & B Luting Cement. Below is a table which shows a side-by-side comparison of the technological characteristics.

Technological Characteristic	**C & B Luting Cement**	**Post Cement Hi-X**
Intended Use	Cementation of fixed restorations of precious, semi-precious and non-precious metals and of porcelain and composite fixed prostheses.	Cementation of posts and cementation of precious, semi-precious and non-precious metal posts
Chemical Composition	Self-cured	Self-cured
Physical/Mechanical Properties	High strength, resistant to wear and abrasion	High strength, resistant to wear and abrasion

Working Time (room temperature)	3-4 minutes	2.5-3.0 minutes
Setting Time (room temperature)	5-7 minutes	4.5-5.0 minutes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1999

Ms. Kathryn B. Patterson
Regulatory Affairs Manager
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K992248
Trade Name: Post Cement Hi-X
Regulatory Class: II
Product Code: EBF
Dated: July 2, 1999
Received: July 6, 1999

Dear Ms. Patterson:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

Attachment 2 – Indications for Use

Indications for Use

510(k) Number (if known): K992248

Device Name: Post Cement Hi-X Dental Cement

Indications for Use:

1. Cementation of posts
2. Cementation of metal posts fabricated with precious, semi-precious or non-precious metals

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Prosser

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992248