FEB 0 6 2003

CONFIDENTIAL

Section 5-1

K024046

Contact: Stephen D. Smith

SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 190 and 21 CFR par 807.92

Trade Name: **BISCOVER XT/TESCERA GLAZING RESIN**
Common Name: **GLAZE**
Classification name: **COATING MATERIAL FOR RESIN FILLINGS**
Class II per 21 CFR 872.3310

Description of Applicant Device:
BISCOVER XT/TESCERA GLAZING RESIN is a solution of methyl methacrylate and urethane acrylate supplied in a bottle.

Intended uses of Applicant Device:
It is applied with a brush to seal the surface of indirect composite restorations, bis acryl/acrylic provisional restorations and processed acrylic appliances.

Predicate Devices: EXTORAL/TESCERA GLAZING RESIN, MODEL T-1804 (K014144 manufactured by AFP Imaging Corp.) cleared by FDA on 02/07/2002

Significant Performance Characteristics:

	BISCOVER XT/TESCERA GLAZING RESIN	**EXTORAL/ TESCERA GLAZING RESIN**
Intended Use	Resin sealant.	Resin sealant.
Product Description	Clear solution.	Clear solution.
Delivery System	Brush	Brush

Side by side comparisons of BISCOVER XT/TESCERA GLAZING RESIN to the predicate device EXTORAL/TESCERA GLAZING RESIN clearly demonstrates that the applicant device is substantially equivalent to the legally marketed devices. The ingredients of BISCOVER XT/TESCERA GLAZING RESIN were tested for biocompatibility and were found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of BISCOVER XT/TESCERA GLAZING RESIN.

Stephen D. Smith
Manager of Regulatory Affairs
Bisco, Inc.
847 534 6146

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2003

Mr. Steve Smith
Manager of Regulatory Affairs
Bisco, Incorporated
1100 W. Irving Park Road
Schaumburg, Illinois 60193

Re: K024046
Trade/Device Name: BIScover™ XT/TESCERA™ Glazing Resin
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: December 04, 2002
Received: December 06, 2002

Dear Mr. Smith:

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,

Susan Runner, DDS, MA
Interim 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): K024046

Device Name: BISCOVER XT/TESCERA GLAZING RESIN

Indications For Use:

TO SEAL THE SURFACE OF INDIRECT COMPOSITE RESTORATIONS, BIS ACRYL/ACRYLIC PROVISIONAL RESTORATIONS AND PROCESSED ACRYLIC APPLIANCES.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Kevin Mulvey for NSR

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

510(k) Number: K024046