K101485

Bringing **Science** to the *Art* of Dentistry™

AUG 26 2010

510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6000 Fax: 847-534-6111
Date Prepared:	26 May 2010
Trade Name:	**Bisco Etchants**
Common Name:	Phosphoric Acid Semi-Gel
Product Code:	KLE
Classification/Name:	Resin Tooth Bonding Agent **Class II per 21 CFR 872.3200**

Description of Applicant Device:

The **Bisco Etchants** are phosphoric acid semi-gels that effectively remove the smear layer, etch and demineralize enamel and dentin, to produce the necessary microretentive surface for successful bonding.

Indications for use:

The principle uses of the **Bisco Etchants** are:

1. Etching and cleaning of dentin and enamel
2. Cleaning of restorative surfaces prior to bonding

Substantial Equivalence

All components of the **Bisco Etchants** are found in legally marketed predicate devices. The **Bisco Etchants** are based upon industry standard chemistry and has similar technological characteristics as other legally marketed devices. Information is provided in this 510(k) submission demonstrating that the **Bisco Etchants** are substantially equivalent to the predicate devices Ecliptomer (K0945604) and to Bisco Universal Bond 3 (K923842) in terms of intended use, indications for use, and chemical composition. An investigation of the physical properties of the **Bisco Etchants** demonstrated that the concentration of phosphoric acid used is sufficient to clean and to expose dentin tubules, demineralize enamel, and to remove the smear layer. Additional studies demonstrate the ability of **Bisco Etchants** to clean restorative surfaces.

The conclusion of the safety evaluation is that the **Bisco Etchants** are safe for its intended use.

Side by side comparisons clearly demonstrate that the applicant device is substantially equivalent to Ecliptomer and to Bisco Universal Bond 3. It is concluded that the information supplied in this submission has proven the safety and efficacy of this product.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Schiltz-Taing
Regulatory Affairs Coordinator
BISCO, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

AUG 26 2010

Re: K101485
Trade/Device Name: Bisco Etchants
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE
Dated: August 16, 2010
Received: August 18, 2010

Dear Ms. Schiltz-Taing:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101485

510 (k) Number (if known): K101485

Device Name: **Bisco Etchants**

Indications for Use:

Bisco Etchants consist of semi-gel phosphoric acids.

The principle uses of the **Bisco Etchants** are:

1. Etching and cleaning of dentin and enamel
2. Cleaning of restorative surfaces prior to bonding

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)

R S Betz DDS for Dr. Susan Runner

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

510(k) Number: K101485