K091705

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AUG 2 8 2009

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:	June 9, 2009
Trade Name:	**Primer Plus**
Common Name:	Universal Restoration Primer
Product Code:	KLE
Classification/Name:	Resin tooth bonding Agent **Class II per 21 CFR 872.3200**

Description of Applicant Device:

The **Primer Plus** is a universal restoration primer.

The principle uses of the **Primer Plus** are:

1. Indirect restorations (such as composite, endodontic posts, metal/metal alloys, porcelain, zirconia, alumina, ceramics, and hybrid ceramics).
2. Intraoral repairs of fractured crowns and bridges (such as metals/metal alloys, porcelain, zirconia, alumina, ceramics, hybrid ceramics, or composite resin).

Substantial Equivalence

All components of the **Primer Plus** are found in legally marketed predicate devices. The **Primer Plus** is based upon industry standard monomer chemistry and has similar technological characteristics as other legally marketed devices. Information is provided in this 510(k) submission demonstrating that the **Primer Plus** is substantially equivalent to the predicate devices Clearfil Ceramic Primer (K061906) and One Step Plus (K011159) in terms of intended use, indications for use, chemical composition and physical properties.

An evaluation of biocompatibility was conducted to determine the safety of the **Primer Plus** using FDA and internationally recognized guidelines. The conclusion of the safety evaluation and subsequent testing is that the **Primer Plus** is safe for its intended use.

Side by side comparisons clearly demonstrate that the applicant device is substantially equivalent to other legally marketed devices. It is concluded that the information supplied in this submission has proven the safety and efficacy of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - 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 2 8 2009

Re: K091705
Trade/Device Name: Primer Plus
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: June 9, 2009
Received: June 10, 2009

Dear Ms. 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.

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting 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): K091705

Device Name: Primer Plus

Indications for Use:

Primer Plus is a universal restoration primer.

The principle uses of the **Primer Plus** are:

1. Indirect restorations (such as composite, endodontic posts, metal/metal alloys, porcelain, zirconia, alumina, ceramics, and hybrid ceramics)
2. Intraoral repairs of fractured crowns and bridges (such as metals/metal alloys, porcelain, zirconia, alumina, ceramics, hybrid ceramics, or composite resin)

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)

Kevin Mundy for NSE

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

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