Food and Drug Administration
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September 9, 2016

Bisco, Inc.
Ryan Hobson
Regulatory Affairs Product Registration Coordinator
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K161051
Trade/Device Name: All-Bond Universal w/ BAC
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: August 8, 2016
Received: August 10, 2016

Dear Ryan Hobson:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161051

Device Name
All-Bond Unviersal w/BAC

Indications for Use *(Describe)*
1. all direct restorations
2. all indirect restorations
3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites)
4. desensitizing/sealing of tooth structure
5. protective varnish for glass ionomer fillings
6. priming of enamel for orthodontic use

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K161051

510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Ryan Hobson RA Product Registration Coordinator Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193 Tel: 847-534-6143 Fax: 847-534-6143
Date Prepared:	8 September 2016
Trade Name:	**All-Bond Universal w/BAC**
Common Name:	Light Curable Dental Adhesive w/BAC
Product Code:	KLE
Classification/Name:	Resin Tooth Bonding Agent **Class II per 21 CFR 872.3200**

Predicate Devices:

Primary Predicate:

DREAMBOND by Bisco, Inc. K112118, Agent, Tooth Bonding Resin - KLE

Reference Predicate:

PEAK UNIVERSAL BOND (Light Cure Resin Adhesive and Chlorhexidine), by Ultradent, K100752, Agent, Tooth Bonding Resin - KLE

Indications for Use:

ALL-BOND UNIVERSAL w/BAC adhesive is used for:

1. all direct restorations
2. all indirect restorations
3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites)
4. desensitizing/sealing of tooth structure
5. protective varnish for glass ionomer fillings
6. priming of enamel for orthodontic use

510 (k) SUMMARY (continued)

The indications for use of **All-Bond Universal w/BAC** are the same as those for its predicates and are summarized in the table below:

DREAMBOND (K112118)	All-Bond Universal w/BAC	Peak Universal Bond (K100752)
1. all direct restorations 2. all indirect restorations 3. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites) 4. desensitizing/sealing of tooth structure 5. protective varnish for glass ionomer fillings 6. priming of enamel for orthodontic use	7. all direct restorations 8. all indirect restorations 9. intra-oral repairs (i.e. repair of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites) 10. desensitizing/sealing of tooth structure 11. protective varnish for glass ionomer fillings 12. priming of enamel for orthodontic use	Peak™ Universal Bond bonds to the following materials: • Dentin and enamel • Porcelain • Metal • Composite

Description of Applicant Device:

BISCO's **ALL-BOND UNIVERSAL w/BAC** is a light-cured single-component dental bonding agent that combines etching, priming, and bonding with benzalkonium chloride (BAC) in one bottle. **ALL-BOND UNIVERSAL w/BAC** is an ethanol/water-based dental adhesive which bonds to dentin and cut and un-cut enamel. **ALL-BOND UNIVERSAL w/BAC** has been designed to be fully compatible with light-cured, self-cured and dual-cured composite materials. **ALL-BOND UNIVERSAL w/BAC** can be used for the bonding of both direct and indirect restorations. **ALL-BOND UNIVERSAL w/BAC** may be used with or without phosphoric acid etchant.

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510 (k) SUMMARY (continued)

Technological Characteristics:

Comparisons of the chemical composition of **ALL-BOND UNIVERSAL w/BAC** to the predicates is provided in the following table:

Chemical Composition	DREAMBOND (K112118)	Peak Universal Bond (K100752)	All-Bond Universal w/BAC
Method of polymerization	Light Cured	Light Cured	Light Cured
Resin composition	Unfilled, multifunctional methacrylate resin	Filled, multifunctional methacrylate resin	Unfilled, multifunctional methacrylate resin
Solvent	Ethanol based	Ethanol based	Ethanol based
Method of application	Single component adhesive	Multi-component, primer required	Single component adhesive
Bond Enhancer	Not applicable	Chlorohexidine	Benzalkonium Chloride

Physical / Mechanical Property Comparison	DREAMBOND (K112118)	Peak Universal Bond (K100752)	All-Bond Universal w/BAC
Film thickness	2.6µm	17.0µm	3.4µm
Etch Methods	Self-etch and total-etch	Self-etch and total-etch	Self-etch and total-etch

The difference in chemical composition as compared to the DREAMBOND is the addition of Benzalkonium. Both DREAMBOND and **ALL-BOND UNIVERSAL w/BAC** have the same technological characteristics before the addition of Benzalkonium Chloride. All-Bond Universal w/BAC uses Benzalkonium Chloride while Peak Universal Bond (K100752) uses Chlorohexidine however; both are cationic surface-acting agents and both have a long history of use in dental medical devices. Peak Universal Bond (K100752) is a filled resin, All-Bond Universal w/BAC and DREAMBOND are both unfilled resins, the lack of filler does not affect intended use and performance data shows the materials are equivalent. All-Bond Universal w/BAC is a single component system, requiring no additional primer in self-etch mode and fewer steps in its use compared to Peak Universal Bond (K100752).

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510 (k) SUMMARY (continued)

Performance Data:

The following physical/mechanical properties of **All-Bond Universal w/BAC** were tested:

Physical / Mechanical Property	All-Bond Universal w/BAC
Bond Strength (Modified ISO 29022:2013)	All-Bond Universal w/BAC is equivalent to the primary and reference predicate.
Moisture Tolerance (Modified ISO 29022:2013)	All-Bond Universal w/BAC is equivalent to the primary and reference predicate.
Film Thickness (ISO 4049:2009)	All-Bond Universal w/BAC meets the requirements of ISO 4049:2009 for Film Thickness.
Water Sorption / Solubility (ADA/ANSI Specification No. 27)	All-Bond Universal w/BAC is equivalent to the primary predicate.
Immediate Bond Strength (Modified ISO 29022:2013)	All-Bond Universal w/BAC is equivalent to the primary and reference predicate.
Bond Strength Durability	Reference predicate showed a 23% reduction in bond strength, primary predicate showed a 27% reduction in bond strength, and All-Bond Universal w/BAC showed a 4% increase in bond strength on completion of the test.
Solvent Evaporation	All-Bond Universal w/BAC is equivalent to the primary and reference predicate.
pH	All-Bond Universal w/BAC is equivalent to the primary predicate.

Biocompatibility:

An evaluation of biocompatibility was conducted using ISO 7405:2008 and ISO 10993-1 to determine the biocompatibility of All-Bond Universal w/BAC. It is concluded from the evaluation and the results of the Oral Toxicity Study (10 rats, 7 days) that **All-Bond Universal w/BAC** was not toxic in this test.

Conclusion:

It is concluded from review of the predicate device indications, chemical composition, biocompatibility, and physical properties that All-Bond Universal w/BAC to be substantially equivalent to the predicate devices.

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