K131734

APR 11 2014

BISCO

510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6146 Fax: 847-534-6146
Date Prepared:	26 August 2013
Trade Name:	**All-Bond Universal SC**
Common Name:	Self and Light Curable Dental Adhesive
Product Code:	KLE
Classification/Name:	Resin Tooth Bonding Agent **Class II per 21 CFR 872.3200**

Predicate Devices:

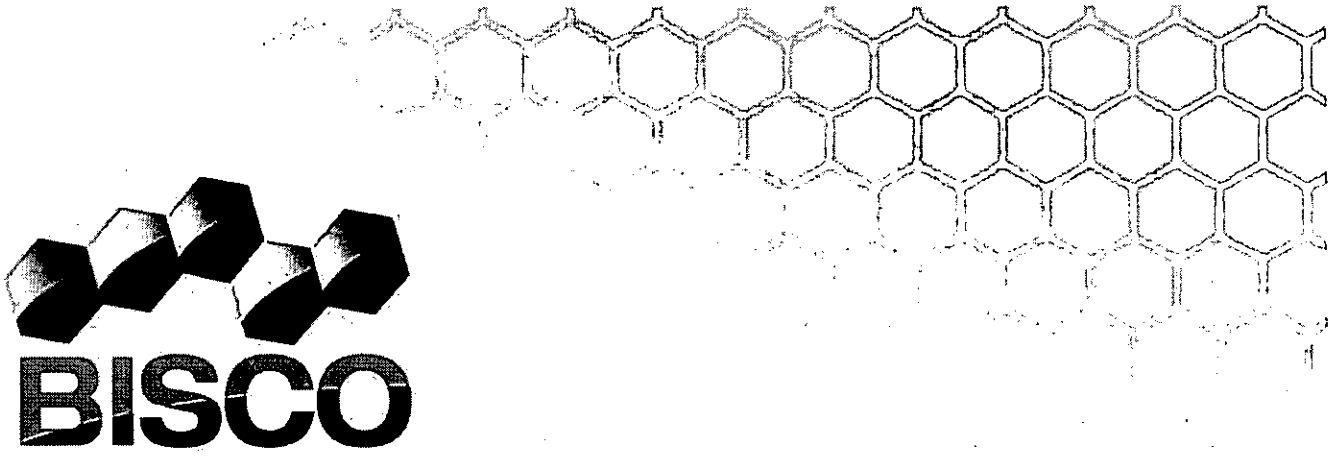
All-Bond Universal SC is substantially equivalent to:

ACE Bond SE by Bisco, Inc. Schaumburg IL K063780

Indications for Use:

All-Bond Universal SC adhesive is used for:

- Direct Restorations (e.g. resin-based composite, resin-modified glass ionomer, core build-ups)
- Indirect Restorations (e.g. metal, glass, ceramics, zirconia/alumina)
- Bonding Resin or Primer for Substrates
- Desensitization/Sealing of Tooth
- Intraoral Repair (e.g. chipped porcelain, additions to direct restorations)



510 (k) SUMMARY (continued)

Description of Applicant Device:

All-Bond Universal SC is an auto-polymerizing adhesive with a light-curing alternative. It is designed for the dentist who prefers not to light cure the adhesive layer under indirect restorations. **All-Bond Universal SC** has a low film thickness (<5 µm). **All-Bond Universal SC** has a chemical formulation that allows the adhesive to be used in either self-etch or total-etch mode, based on the clinical situation and dentist preference. **All-Bond Universal SC** is compatible with light-cured, self-cured, dual-cured resin composite and cement base materials for direct and indirect procedures without any additional activators.

Technological Characteristics:

All components of **All-Bond Universal SC** are based upon industry standard chemistry. Comparisons of the chemical composition of **All-Bond Universal SC** to the predicate is provided in the following table:

Chemical Composition	ACE Bond SE K063780	All-Bond Universal SC
Light-Cured	X	X
Auto-Polymerizing		X
Unfilled, multifunctional methacrylate resin	X	X
Ethanol based	X	X
Two component adhesive	X	X
Color Changes from pink to clear after cure	X	---

Performance Data:

The physical/mechanical properties of **All-Bond Universal SC** were tested in the lab using R&D testing protocols to determine shear bond strength and microleakage. A modified technique form ISO 4049 was used to determine film thickness. The information provided in this 510(k) for **All-Bond Universal SC** compared to the predicate demonstrate that it is substantially equivalent for its indications for use. A comparison of the physical/mechanical properties are included below:

Physical / Mechanical Property Comparison	ACE Bond SE K063780	All-Bond Universal SC
Solvent Based Formulation (solvent>40% by weight)	X	X
Self-Etching Dental Adhesive	X	X
Total-Etching Dental Adhesive		X

BISCO, Inc.
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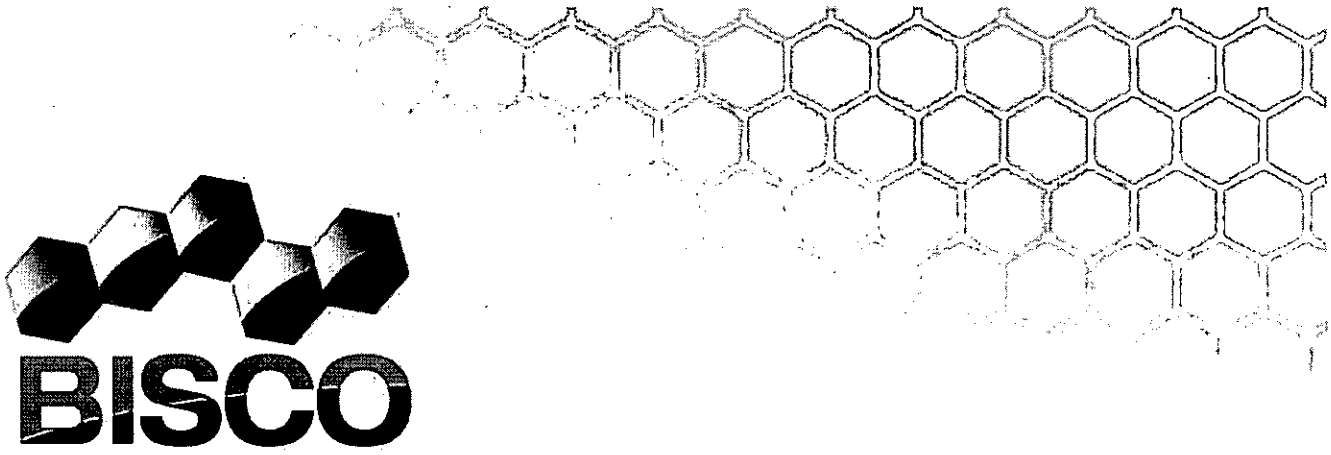

510 (k) SUMMARY (continued)

Biocompatibility:

An evaluation of biocompatibility was conducted using ISO 7405:2008 to determine the safety of All-Bond Universal SC. It is concluded from the safety evaluation and the results of the Oral Toxicity Study (10 rats, 14 days) that **All-Bond Universal SC** was not toxic in this test."

Conclusion:

Side by side comparisons clearly demonstrate that the applicant device is substantially equivalent to the other legally marketed devices. It is concluded that the information supplied in this submission has demonstrated that All-Bond Universal SC is substantially equivalent to the legally marketed predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 11, 2014

Bisco, Incorporated
Ms. Michelle Schiltz-Taing
1100 W. Irving Park Road
Schaumburg, IL 60193

Re: K131734
Trade/Device Name: All-Bond Universal SC
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: March 3, 2014
Received: March 12, 2014

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 contact 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K131734

Device Name: All-Bond Universal SC

Indications for Use:

All-Bond Universal SC adhesive is used for:

- Direct Restorations (e.g. resin-based composite, resin-modified glass ionomer, core build-ups)
- Indirect Restorations (e.g. metal, glass, ceramics, zirconia/alumina)
- Bonding Resin or Primer for Substrates
- Desensitization/Sealing of Tooth
- Intraoral Repair (e.g. chipped porcelain, additions to direct restorations)

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)

Sheena A. Green -S
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