CONFIDENTIAL

JAN 17 2002

K013519

Section 5-1

Bisco, Inc.
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Contact: Stephen D. Smith, Regulatory Affairs Manager

Specialist in Adhesive and Composite Technology

Bringing Science to the Art of Dentistry™

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:	**SIMPLE**
Common Name:	**No Rinse Self-Etching Primer**
Classification name:	**Resin Tooth Bonding Agent**
	Class II per 21 CFR 872.3200

Description of Applicant Device:
A two bottle (or unit dose container), no rinse self-etching primer for use with light cured dental adhesives.

Intended uses of Applicant Device:

- Direct and Indirect Restorations: to etch enamel/dentin prior to bonding with ONE STEP® for use with light-cured composite materials
- Indirect Restorations: when used with an adhesive, to seal a preparation when using a light-cured composite cement
- Desensitization: when used in combination with adhesive, to treat hypersensitive and/or exposed root surfaces.

Predicate Devices: Clearfil™ SE BOND K990040 (clearance date of 2/4/99)

Significant Performance Characteristics:

	SIMPLE	Clearfil SE BOND
Intended Use:	Designed to reduce steps in preparing dentin and enamel for composite adhesion	Designed to reduce steps in preparing dentin and enamel for composite adhesion
Product Description:	One clear yellow solution One white slurry	Two clear solutions
Delivery System:	Two solutions in separate bottles or in a two-chamber unit dose package.	Two solutions in separate bottles package.

Side by side comparisons of SIMPLE to the predicate device Clearfil SE BOND clearly demonstrates that the applicant device is substantially equivalent to the legally marketed devices. The ingredients of Simple were biocompatibility tested, cytotoxicity and acute oral toxicity, and were found to be non-toxic.

It is concluded that the information supplied in this submission has proven the safety and efficacy of SIMPLE.

Stephen D. Smith
Manager of Regulatory Affairs

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Mr. Stephen D. Smtih
Manager of Regulatory Affairs
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K013519
Trade/Device Name: Simple
Regulation Number: 872.3200
Regulation Name: Resin Dentin Bonding System
Regulatory Class: II
Product Code: KLE
Dated: October 17, 2001
Received: October 23, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013519

Device Name: SIMPLE

Indications For Use:

1. Direct and Indirect Restorations: to etch enamel/dentin prior to bonding with ONE-Step and some other fifth generation adhesives for use with light-cured composite materials

2. Indirect Restorations: when used with an adhesive, to seal a preparation when using a light-cured composite cement.

3. Densensitization: when used in combination with adhesive, to treat hypersensitive and/or exposed root surfaces.

(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
(510(k) Number K013519