510(k) Submission for **First Step**
Bisco, Inc., 1100 W. Irving Park Road
Schaumburg, IL. 60193

SEP 1 7 2001

510(k) SUMMARY K012032

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Trade Name: **First Step**
Common Name: **BRACKET ADHESIVE RESIN AND TOOTH CONDITIONER**

Classification Name: **BRACKET ADHESIVE RESIN AND TOOTH CONDITIONER**
21 CFR 872.3750

Description of Applicant Device:
A two bottle, self-etching primer for use with light-curing and self-curing direct bonding orthodontic adhesives.

Intended Uses of Applicant Device:
Intended to be used primarily for etching and priming of enamel for the application of an orthodontic attachment.

Predicate Device:
Transbond™™ Plus Self Etching Primer

Scientific Concepts and Significant Performance Characteristics:

	FIRST STEP	Transbond™ Plus Self Etching Primer
Intended Use	A self-etching primer for use with light-curing and self-curing direct bonding orthodontic adhesives.	A self etching primer for use only with light-curing direct bonding orthodontics adhesives
Chemical Composition	Combination of an acid and methacrylate.	Combination of an acid and methacrylate.
Mechanical/ Physical Properties	• Combines etching and priming in one easy step • No rinsing • Etch and primes simultaneously • Outstanding bond strengths	• Combines etching and priming in one easy step • No rinsing • Etches and primes simultaneously • Outstanding bond strengths

510(k) SUMMARY, continued

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Side by side comparisons of First Step to the predicate device Transbond™ Plus Self Etching Primer clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device.

Shear bond strength testing results were reviewed. Based on the results of the testing it was concluded that First Step performs as well as the predicate device and therefore has proven its safety and efficacy.

Kathy Joung, Ph.D
1-800-BIS-DENT or 847-534-6106
Fax: 847-891-6865

June 25,2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2001

Ms. Kathy Long
Director of Quality Systems
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K012032
Trade/Device Name: First Step
Regulation Number: 872.3750
Regulation Name: Adhesive, Bracket and Tooth Conditioner Accessory
Regulatory Class: II
Product Code: DYH
Dated: June 25, 2001
Received: June 29, 2001

Dear Ms. Long:

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.

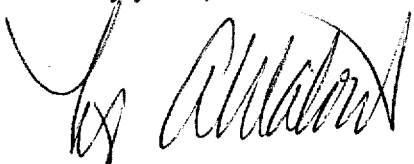
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 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 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

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Indications for Use

510(k) Number (if known): ~~Not Applicable~~ K012037

Device Name: First Step

Indications for Use:

A two bottle, self-etching primer for use with light-curing and self-curing direct bonding orthodontic adhesives.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012037