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

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

May 23, 2017

Re: K162598
Trade/Device Name: HAPI Seal
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit And Fissure Sealant And Conditioner
Regulatory Class: Class II
Product Code: EBC
Dated: May 23, 2017
Received: May 23, 2017

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,

Mary S. Runner -S

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2017.05.23 12:25:35 -04'00'

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)*
K162598

Device Name
HAPI Seal

Indications for Use *(Describe)*
Pit and fissure sealant

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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K162598

510(k) SUMMARY

Applicant: Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193

Contact Person: Ryan Hobson
Tel: 847-534-6143
Fax: 847-534-6143

Date Prepared: 19 May 2017

Trade Name: **HAPI Seal**
Common Name: Pit & Fissure Sealant
Product Code: EBC
Classification/Name: Pit and fissure sealant and conditioner
Class II per 21 CFR 872.3765

Predicate Devices:

HAPI Seal is substantially equivalent to:

Clinpro by 3M Company, K992326

Indications for Use:
Pit and fissure sealant

Description of Applicant Device:

HAPI Seal is a light-cured, fluoride containing, resin-based pit & fissure sealant designed for sealing the enamel pits and fissures of teeth.

Comparison of Technological Characteristics:

Indications for use
HAPI Seal indications for use are identical to that of the predicate device and summarized in the table below:

Clinpro K992326	HAPI Seal
Pit and fissure sealant	Pit and fissure sealant

All components of HAPI Seal are based upon industry standard chemistry. The chemical composition of HAPI Seal is similar to Clinpro, methacrylate based chemistry, and is summarized in the table below:

510(k) SUMMARY (continued)

Chemical Composition	Clinpro K992326	HAPI Seal
Filler	Silica	Silica
Resin composition	Methacrylate Resin	Methacrylate Resin
Polymerization Method	light cured	light cured
Ions Released	Fluoride	Fluoride

Physical Mechanical Property	Clinpro K992326	HAPI Seal
Depth of Cure	Meets ISO 6874:2015	Meets ISO 6874:2015
Ions Released	Fluoride releasing	Fluoride releasing
Polymerization time	20 second light cure	20 second light cure
Bonding	Bonds to enamel	Bonds to enamel

Performance Data:

HAPI Seal meets ISO 6874:2015 "Dentistry - Polymer-based pit and fissure sealants." Shear bond strength was tested based upon ISO 29022:2013 Dentistry – Adhesion – Notched-edge shear bond strength test. Additionally, Light Curability, Ambient Light Sensitivity, Depth of Cure, Flexural Strength, Flexural Modulus, Cumulative Fluoride Release, Compressive Strength, Surface Hardness, and Shrinkage were tested and demonstrate HAPI Seal is substantially equivalent to the predicate device. A comparison of the physical/mechanical properties of HAPI Seal to the predicate device is provided in the table below.

Physical / Mechanical Property	HAPI Seal
Shear Bond Strength (Modified ISO 29022)	HAPI Seal is equivalent to the predicate.
Light Curability (Cure time)	HAPI Seal is equivalent to the predicate.
Ambient Light Sensitivity	HAPI Seal is equivalent to the predicate
Depth of Cure (ISO 6874:2015)	HAPI Seal meets the requirements of ISO 6874:2015.
Flexural Strength (ISO 4049:2009)	HAPI Seal meets the requirements of ISO 4049:2009 for Flexural Strength.
Flexural Modulus (ANSI/ADA Spec No. 27)	HAPI Seal is equivalent to the predicate
Cumulative Fluoride Release	HAPI Seal is equivalent to the predicate.
Compressive Strength (ANSI/ADA Spec No. 27)	HAPI Seal is equivalent to the predicate.
Surface Hardness (Barcol-Colman 934-1)	HAPI Seal is equivalent to the predicate.
Shrinkage (Volumetric)	HAPI Seal is equivalent to the predicate.

BISCO, Inc.
1100 W. Irving Park Road
Schaumburg, IL 60193 U.S.A.
800-247-3368 or 847-534-6000
Fax: 847-891-5049
www.bisco.com

510(k) SUMMARY (continued)

Biocompatibility:
An evaluation of biocompatibility was conducted using ISO 7405:2008 and ISO 10993-1 to determine the biocompatibility of HAPI Seal. Cytotoxicity and Oral Toxicity testing was completed. It is concluded from the biocompatibility evaluation and the results of Oral Toxicity Study (10 mice, 14 days) that HAPI Seal was not toxic in this test.

Conclusion:
It is concluded from review of the predicate device indications, chemical composition, biocompatibility, and physical properties that HAPI is substantially equivalent to the predicate devices.

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