DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 4, 2017

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

Re: K171147
Trade/Device Name: REVEAL Bulk
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: May 10, 2017
Received: May 11, 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,

Andrew I. Steen -S

for Lori Wiggins, MPT, CLT
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)*
K171147

Device Name
REVEAL Bulk

Indications for Use *(Describe)*
1) Direct anterior and posterior restorations (including occlusal surfaces)
2) Base/liner under direct restorations
3) Core build-ups
4) Splinting
5) Indirect restorations including inlays, onlays and veneers
6) Restorations of deciduous teeth
7) Extended fissure sealing in molars and premolars
8) Repair of defects in porcelain restorations, enamel, and temporaries

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.

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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:	10 May 2017
Trade Name:	**REVEAL Bulk**
Common Name:	Light-Cured Bulk Fill Composite
Product Code:	EBF
Classification/Name:	Tooth Shade Resin Material **Class II per 21 CFR 872.3690**

Predicate Devices:

REVEAL Bulk is substantially equivalent to:

Filtek Bulk Fill Posterior Restorative, by 3M ESPE, K141081

Indications for Use:

1) Direct anterior and posterior restorations (including occlusal surfaces)
2) Base/liner under direct restorations
3) Core build-ups
4) Splinting
5) Indirect restorations including inlays, onlays and veneers
6) Restorations of deciduous teeth
7) Extended fissure sealing in molars and premolars
8) Repair of defects in porcelain restorations, enamel, and temporaries

The indications for use of REVEAL Bulk are identical to those for Filtek Bulk Fill (K141081) and are summarized in the table below:

Filtek Bulk Fill (K141081)	REVEAL Bulk
• Direct anterior and posterior restorations (including occlusal surfaces) • Base/liner under direct restorations • Core build-ups • Splinting • Indirect restorations including inlays, onlays and veneers • Restorations of deciduous teeth • Extended fissure sealing in molars and premolars • Repair of defects in porcelain restorations, enamel, and temporaries	1) Direct anterior and posterior restorations (including occlusal surfaces) 2) Base/liner under direct restorations 3) Core build-ups 4) Splinting 5) Indirect restorations including inlays, onlays and veneers 6) Restorations of deciduous teeth 7) Extended fissure sealing in molars and premolars 8) Repair of defects in porcelain restorations, enamel, and temporaries

Description of Applicant Device:

REVEAL Bulk is a light-activated restorative composite, optimized to allow for simpler and faster posterior restorations. **REVEAL Bulk** is intended to combine superior levels of handling, depth of cure, and polishability to perform as an optimum functional and aesthetic bulk fill composite.

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

Technological Characteristics:

All components of REVEAL Bulk are based upon industry standard chemistry. The chemical composition of REVEAL Bulk is similar to Filtek Bulk Fill (K141081) summarized in the table below:

Chemical Composition	Filtek Bulk Fill (K141081)	REVEAL Bulk
Filler	Inorganic glass fillers (Ceramic, Silica, Zirconia, Ytterbium Fluoride)	Inorganic glass fillers (Barium and Ytterbium Fluoride)
Resin composition	Methacrylate based resin matrix	Methacrylate based resin matrix
Adhesion	Requires use of dental adhesive	Requires use of dental adhesive
Polymerization Method	Light induced polymerization to form a hard composite.	Light induced polymerization to form a hard composite.

Physical Mechanical Property	Filtek Bulk Fill (K141081)	Reveal Bulk
Radiographic Appearance	Radiopaque	Radiopaque
Depth of Cure	4 mm	5 mm
Delivery system	Syringe and unit-dose	Syringe and unit-dose

The difference in filler is REVEAL Bulk's use of Barium Glass, an industry standard filler and is substantially equivalent in performance to Filtek Bulk Fill's fillers. Additionally, REVEAL Bulk's depth of cure, from a single point cure, is 5mm as determined by ISO 4049:2009(E), an improvement, and does not raise new questions of safety or efficacy. Both REVEAL Bulk and the predicate device are methacylate based light cured composite devices that require the use of a dental adhesive and are available in syringes and unit dose.

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Performance Data:

The following physical/mechanical properties of REVEAL Bulk were tested:

Physical / Mechanical Property	REVEAL Bulk
Diametral Tensile Strength	REVEAL Bulk is equivalent to the predicates.
Flexural Strength / Flexural Modulus (ISO 4049:2009)	REVEAL Bulk meets the requirements of ISO 4049:2009 for Flexural Strength. REVEAL Bulk is equivalent to the predicate for Flexural Modulus.
Radiopacity (ISO 4049:2009)	REVEAL Bulk meets the requirements of ISO 4049:2009 for Radiopacity.
Water Sorption and Solubility (ISO 4049:2009)	REVEAL Bulk meets the requirements of ISO 4049:2009 for Water Sorption and Solubility.
Depth of Cure (ISO 4049:2009)	Predicate: 4 mm, REVEAL Bulk: 5 mm
Volumetric Shrinkage	REVEAL Bulk is equivalent to the predicate.
Compressive Strength	REVEAL Bulk is equivalent to the predicate.
Wear	REVEAL Bulk is equivalent to the predicate.
Polish Retention	REVEAL Bulk is equivalent to the predicate.
Surface Hardness	REVEAL Bulk is equivalent to the predicate.
Cusp Deflection	REVEAL Bulk is equivalent to the predicate.

Biocompatibility:

An evaluation of biocompatibility was conducted using ISO 7405:2008 and ISO 10993-1 to determine the biocompatibility of REVEAL Bulk. It is concluded from the evaluation and the results of the Cytotoxicity testing that REVEAL Bulk meets the requirements of the testing.

Conclusion:

It is concluded from review of the predicate device indications, chemical composition, biocompatibility, and physical properties that REVEAL Bulk is substantially equivalent in safety and effectiveness to the predicate device.

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