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 14, 2017

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

Re: K163171
Trade/Device Name: CeraClean
Regulation Number: 21 CFR 872.3260
Regulation Name: External Cleaning Solution
Regulatory Class: Class II
Product Code: PME
Dated: March 23, 2017
Received: March 20, 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 yours,

Michael J. Ryan -S

for 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)*
K163171

Device Name
CeraClean

Indications for Use *(Describe)*
Ceraclean is an extraoral cleaner of pre-treated ceramic, zirconia and metal restoration surfaces which have been contaminated during intraoral try-in.

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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510(k) SUMMARY

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

Contact Person: Ryan Hobson
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Tel: 847-534-6143
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Date Prepared: 13 April 2017

Trade Name: **CeraClean**
Common Name: Restoration Cleaner
Product Code: PME
Classification/Name: External Cleaning Solution
Class II per 21 CFR 872.3260

Predicate Device:

Resolve 2.0, K152322 by Denali Corporation

CeraClean Indication for Use:

CeraClean is an extraoral cleaner of pre-treated ceramic, zirconia and metal restoration surfaces which have been contaminated during intraoral try-in.

Description of Applicant Device:

CeraClean is used outside the mouth, as an extraoral cleaning gel suitable for non-abrasive cleaning of the bonding surfaces of prosthetic restorations after intraoral try-in. CeraClean is applied through a single-use tip or application to the prosthetic restorations and rinsed off prior to the application of a primer or cement for final placement of the restoration.

510(k) SUMMARY (continued)

Comparison of Technological Characteristics:

Indications for Use

Resolve 2.0 K152322 (predicate device)	CeraClean
Resolve 2.0 is recommended for use on dental restorations, external to the mouth, prior to insertion into the mouth. After applying Resolve 2.0 to cleanse the restoration, the surface of the restoration should be washed thoroughly with water, and then air dried before placement in the mouth.	CeraClean is an extraoral cleaner of pre-treated ceramic, zirconia and metal restoration surfaces which have been contaminated during intraoral try-in.

CeraClean's Indications for Use Statement does not include the cleaning information included in the predicate's statement and list pre-treated ceramic, zirconia and metal restorations instead of just general restorations. These differences are not critical to the intended use of the subject device as equivalent cleaning instructions are included within the instructions for use. The increased specificity list the most common materials used in dental prosthetic restorations and fall within the general indication and no not alter the device risk. The subject device is just as safe and effective as compared to the predicate device.

Chemical Composition

Chemical Composition	Resolve 2.0 K152322 (predicate device)	CeraClean
Composition	Acrylate resin based gel	Water based gel
Viscosity modifier	Silicate	Xanthum Gum
Active ingredient	Chlorohexidine	Potassium Hydroxide
pH after rinsing	Neutral	Neutral
Water Solubility	Water Soluble	Water Soluble
Pigmented	Yes – Pink	Yes - Blue

510(k) SUMMARY (continued)

Comparison of Technological Characteristics (continued):

Physical / Mechanical Property	Resolve 2.0 K152322 (predicate device)	CeraClean
Shear Bond Strength (modified ISO 29022:2013)	Removes saliva contamination	Removes saliva contamination
Method of application	Syringe tip w/brush	Syringe tip or brush
Method of cleaning	Abrasive	Non-abrasive
Method of Removal	Water spray & air dried	Water spray & air dried
Delivery configuration	Syringe	Syringe or Bottle
Removal	Water Soluble	Water Soluble

The major differences between Resolve 2.0 and CeraClean are that Resolve 2.0 is a pigmented acrylate resin based gel that uses silicate as a viscosity modifier, includes Chlorohexidine, and is abrasive. CeraClean however, is a pigmented water based gel that uses xanthum gum as a viscosity modifier and does not require abrasive scrubbing to clean the substrate of saliva contamination in preparation for final restoration placement. The lack of acrylate resins in CeraClean does not raise new questions of safety or effectiveness as both devices are water soluble, used outside the mouth, and rinsed off the restorative device prior to placement in the mouth. CeraClean does not include the antimicrobial agent Chlorohexidine. Both devices are pigmented, water soluble, and cleaned substrates are neutral after rinsing.

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510(k) SUMMARY (continued)

Performance Data:

Shear bond strength was tested based upon ISO 29022:2013 Dentistry – Adhesion – Notched-edge shear bond strength test. Additionally, water solubility and pH (before and after rinse) were tested. A comparison of the physical/mechanical properties of CeraClean to the predicate device is provided in the table below.

Physical / Mechanical Property	CeraClean
Shear Bond Strength (modified ISO 29022:2013)	Substantially equivalent to the predicate device.
Water Solubility	Substantially equivalent to the predicate device.
pH (before rinse / after rinse)	Predicate: pH = 6/7, CeraClean pH = 14/7
SEM EDX	Demonstrates device is removed from substrate.

Biocompatibility:

An evaluation of biocompatibility was conducted using ISO 7405:2008 and ISO 10993-1:2009. It is concluded from the biocompatibility evaluation and the results of the cytotoxicity testing that CeraClean met the requirements of the test.

Conclusion:

It is concluded that the information supplied in this submission has demonstrated that CeraClean is substantially equivalent in design, composition, performance, and intended use to the legally marketed predicate device.