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

August 4, 2015

Bisco Inc.
Ms. Michelle Schiltz-Taing
Regulatory Affairs Product Registration Manager
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K143292
Trade/Device Name: TheraCal DC
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: June 24, 2015
Received: June 26, 2015

Dear Ms. Schiltz-Taing:

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" (21CFR 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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K143292

Device Name: TheraCal DC

Indications for Use:

TheraCal DC is indicated for use for:

1. Pulpotomy
2. Temporary filling material
3. Repair of root perforations
4. Repair of furcation perforations
5. Repair of perforating internal and external resorptions
6. Root-end filling in endodontic surgery
7. Pulp exposures (direct pulp capping)
8. Protective liner (Indirect Pulp Capping) and Base for use under a variety of substrates

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6146 Fax: 847-534-6146
Date Prepared:	03 August 2015
Trade Name:	**TheraCal DC**
Common Name:	Dual-Cured Resin-Modified Calcium Silicate Pulp Protectant
Product Code:	EJK
Classification/Name:	Liner, Cavity, Calcium Hydroxide **Class II per 21 CFR 872.3250**

Predicate Devices:

TheraCal DC is substantially equivalent to:

Primary Predicate: TheraCal LC by Bisco Inc. K063237

Reference Predicates: BioDentine by Septodont K140132

RMGI Low Viscosity (believed to be Activa) by Pulpdent K123265

Pro Root MTA by Dentsply K142178

TheraCal DC is indicated for use for:

1. Pulpotomy
2. Temporary Filling Material
3. Repair of Root Perforations
4. Repair of Furcation Perforations
5. Repair of Perforating Internal and External Resorptions
6. Root-End Filling in Endodontic Surgery
7. Pulp Exposures (Direct Pulp Capping)
8. Protective Liner (Indirect Pulp Capping) and Base for Use Under a Variety of Substrates

510 (k) SUMMARY (continued)

The indications for use of **TheraCal DC** are the same as those for its predicates and are summarized in the table below:

TheraCal LC K063237	Activa K123265	ProRoot MTA K142178	BioDentine K140132	TheraCal DC
1. Liner 2. Pulp Capping Agent	Pulpdent RMGI Low viscosity is a resin-modified glass ionomer preparation used by dental professionals as a liner, base or luting material in dental restorations	root end filling material • for the repair of repair of root canals as an apical plug during apexification • for the repair of root perforations during root canal therapy or as a consequence of internal resorption • as a pulp capping material pulpotomy of primary teeth in the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations	Biodentine is indicated to be used: In the crown: -permanent dentine restoration under composites or inlay/onlay -temporary dentine-enamel restoration -restoration of deep and/or large coronal carious lesions (sandwich technique) -restoration of cervical radicular lesions. -pulp capping. -pulpotomy. In the root: -repair of root perforations -repair of furcation perforations -repair of perforating internal resoprtions -repair of external resorption -apexification -root-end filling in endodontic surgery (retrograde filling)	TheraCal DC is indicated for use for: 1. Pulpotomy 2. Temporary filling material 3. Repair of root perforations 4. repair of furcation perforations 5. repair of perforating internal and external resorptions 6. root-end filling in endodontic surgery 7. pulp exposures (direct pulp capping) 8. Protective liner (indirect pulp capping) and base for use under a variety of substrates

Description of Applicant Device:

TheraCal DC is a biocompatible, dual-cured, resin-modified calcium silicate that is used to treat damaged dentin in both the crown and the root. TheraCal DC's precise placement allows its use in all deep cavity preparations and endodontic repairs. The dual-cure set permits immediate placement and condensation of the restorative material. Its proprietary formulation allows for a command set with a light curing unit while maintaining ease of placement due to its thixotropic properties.

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 TheraCal DC are based upon industry standard chemistry. Comparisons of the chemical composition of TheraCal DC to the predicates are provided in the following table:

Chemical Composition	TheraCal LC K063237	Activa K123265	TheraCal DC
Filler	Portland Cement	Amorphous Silica	Portland Cement
Resin Composition	Hydrophilic resin to facilitate calcium release	Blend of diurethane and other methacrylates with modified polyacrylic acid	Hydrophilic resin to facilitate calcium release
Method of polymerization	Light-Cure	Dual-Cure	Dual-Cure
Method of Application	Bonding agent not required	Bonding agent not required	bonding agent not required
Ions Released	Calcium and hydroxide	Calcium, phosphate, and fluoride	Calcium and hydroxide

Physical / Mechanical Property Comparison	TheraCal LC K063237	Activa K123265	BioDentine K140132	TheraCal DC
Radiographic Appearance (ISO 4049:2009 7.14)	Radiopaque	Radiopaque	Radiopaque	Radiopaque
Ions Released	Calcium releasing	Fluoride containing	Calcium releasing	Calcium releasing
pH	basic	Not reported	basic	basic

The difference in chemical composition as compared to the primary predicate is the addition of industry standard chemicals to make TheraCal DC dual-curable. A reference predicate has been provided that is also dual-cured (Activa).

Performance Data:

The following physical/mechanical properties of TheraCal DC were tested: flexural strength (ISO 4049:2009), compressive strength (ANSI/ADA Spec. No. 27:1993 Appendix A2), dimetral tensile strength (in-house test method), working time (in-house test method), bond strength (in-house test method), radiopacity (ISO 4049:2009), water sorption and solubility (ISO 4049:2009 and ISO 6876:2012), calcium release (in-house test method), and pH (in-house test method). An evaluation of biocompatibility of TheraCal DC was conducted using ISO 7405:2008 and ISO 10993-1:2009. Direct comparison testing demonstrates that TheraCal DC is similar to or greater than the predicate devices.

Physical / Mechanical Property	TheraCal DC
Flexural Strength	TheraCal DC is greater than the predicate devices
Dimetral Tensile Strength	TheraCal DC is greater than the predicate devices
Working Time	Not compared to predicate devices; met the design control inputs
Bond Strength	TheraCal DC shear bond strength is greater than the predicate devices
Radiopacity	Meets the ISO requirements (1 mm of TheraCal DC > 1mm of alumina)
Water Sorption & Solubility	TheraCal DC meets the ISO 4049 requirements for water sorption TheraCal DC meets the ISO 6876 requirements for water solubility
Calcium Release	TheraCal DC is equivalent to the predicate devices
pH Testing	TheraCal DC is equivalent to the predicate devices

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

It is concluded from the evaluation and the results of the cytotoxicity study that TheraCal DC meets the requirements of the testing.

Conclusion:
It is concluded that the information supplied in this submission has demonstrated that TheraCal DC is substantially equivalent to the legally marketed predicate devices because:

- The indications for use are the same to the listed predicates,
- The chemical composition, method of application and method of polymerization is similar to the primary and reference predicate devices.
- Physical properties are equivalent to the predicates.
- The requirements of the biological testing were met.

.

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