



April 5, 2018

Bisco, Inc.
Ryan Hobson
RA Product Registration Manager
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K180344
Trade/Device Name: TheraCal DC
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: Class II
Product Code: EJK
Dated: March 5, 2018
Received: March 7, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -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

Indications for Use

510(k) Number (if known)

K180344

Device Name

TheraCal DC

Indications for Use (Describe)

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

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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Special 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: 5 March 2018

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 DC by Bisco Inc. K143292

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



Special 510(k) SUMMARY (continued)

The indications for use of **TheraCal DC** are identical to the predicate device.

TheraCal DC (K143292)	Modified TheraCal DC
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. apexification 7. root-end filling in endodontic surgery 8. pulp exposures (direct pulp capping)	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. apexification 7. root-end filling in endodontic surgery 8. pulp exposures (direct pulp capping)

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.

Technological Characteristics:

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

Chemical Composition	TheraCal DC (K143292)	Modified TheraCal DC
Filler	Portland Cement	Portland Cement
Resin Composition	Hydrophilic resin to facilitate calcium release	Hydrophilic resin to facilitate calcium release
Method of polymerization	Dual-Cure	Dual-Cure
Method of Application	bonding agent not required	bonding agent not required
Ions Released	Calcium and hydroxide	Calcium and hydroxide

Physical / Mechanical Property Comparison	TheraCal DC (K143292)	Modified TheraCal DC
Radiographic Appearance (ISO 4049:2009 7.14)	Radiopaque	Radiopaque
Ions Released	Calcium releasing	Calcium releasing
pH	basic	basic
Shelf-Life	12 months	18 months



The primary difference between the subject device and the predicate is the stated shelf life.

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 / setting 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 equivalent to the predicate device.

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 from review of the predicate device indications, chemical composition, biocompatibility, and physical properties that TheraCal DC is substantially equivalent in safety and effectiveness to the predicate device.