Tuesday, March 17, 2020

Bisco, Inc.
Diana Vu
RA Registration Specialist
1100 West Irving Park Rd.
Schaumburg, Illinois 60193

Re: K192007
Trade/Device Name: TheraBase / TheraBase Ca
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: December 19, 2019
Received: December 23, 2019

Dear Diana Vu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Srivinas ‘Nandu’ Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192007

Device Name
TheraBase / TheraBase Ca

Indications for Use *(Describe)*

1. Metal crowns, bridges, inlays, onlays (includes porcelain-fused -to- metal and composite-to-metal)
2. Porcelain, Ceramic Crowns, inlays, and onlays (includes alumina and zirconia)
3. Resin crowns, bridges, inlays, and onlays (resin-based composite/composite-ceramic hybrid)
4. Metal (prefabricated or cast) and non-metal/fiber endodontic posts
5. Implant supported restorations
6. Orthodontic Appliances (brackets, bands)
7. Lining and basing applications under restorations

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Diana Vu Tel: 847-534-6091 Fax: 847-534-6091
Date Prepared:	19 December 2019
Trade Name:	**TheraBase; TheraBase Ca**
Common Name:	Self-Adhesive Calcium Releasing Resin Cement and Base/Liner
Product Code:	EMA
Classification/Name:	Dental Cement **Class II per 21 CFR 872.3275**

Predicate Devices:

TheraCem is substantially equivalent to:

Primary Predicate:	TheraCem by Bisco, Inc. K161256
Reference Predicate:	NuSmile Biocem by NuSmile, LTD / Pulpdent K123265

Indications for Use:

1. Metal crowns, bridges, inlays and onlays (includes porcelain-fused-to-metal and composite-to-metal)
2. Porcelain, Ceramic Crowns, inlays and onlays (includes alumina and zirconia)
3. Resin crowns, bridges, inlays and onlays (resin-based composite/composite-ceramic hybrid)
4. Metal (prefabricated or cast) and non-metal/fiber endodontic posts
5. Implant supported restorations
6. Orthodontic Appliances (brackets, bands)
7. Lining and basing applications under restorations

BISCO, Inc.
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www.bisco.com

510 (k) SUMMARY (continued)

The indications for use of TheraBase and TheraBase Ca are the similar to those for TheraCem and NuSmile BioCem and are summarized in the table below:

TheraCem (K161256)	TheraBase	TheraBase Ca	NuSmile BioCem (K123265)
Use TheraCem to cement the following: 1. Metal crowns, bridges, inlays and onlays (includes porcelain-fused-to-metal and composite-to-metal) 2. Porcelain, Ceramic Crowns, inlays and onlays (includes alumina and zirconia) 3. Resin crowns, bridges, inlays and onlays (resin-based composite/composite-ceramic hybrid) 4. Metal (prefabricated or cast) and non-metal/fiber endodontic posts 5. Implant supported restorations 6. Orthodontic Appliances (brackets, bands)	1. Metal crowns, bridges, inlays, onlays (includes porcelain-fused -to- metal and composite-to-metal) 2. Porcelain, Ceramic Crowns, inlays, and onlays (includes alumina and zirconia) 3. Resin crowns, bridges, inlays, and onlays (resin-based composite/composite-ceramic hybrid) 4. Metal (prefabricated or cast) and non-metal/fiber endodontic posts 5. Implant supported restorations 6. Orthodontic Appliances (brackets, bands) 7. Lining and basing applications under restorations	1. Metal crowns, bridges, inlays, onlays (includes porcelain-fused -to- metal and composite-to-metal) 2. Porcelain, Ceramic Crowns, inlays, and onlays (includes alumina and zirconia) 3. Resin crowns, bridges, inlays, and onlays (resin-based composite/composite-ceramic hybrid) 4. Metal (prefabricated or cast) and non-metal/fiber endodontic posts 5. Implant supported restorations 6. Orthodontic Appliances (brackets, bands) 7. Lining and basing applications under restorations	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.

The only change in the indication for use from TheraCem to TheraBase and TheraBase Ca is the addition of "Lining and basing applications under restorations." NuSmile BioCem is added as a reference predicate to demonstrate that it does not raise new questions of safety and effectiveness as it contains the same indication listed as "liner, base."

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510 (k) SUMMARY (continued)

Description of Applicant Device:

TheraBase and TheraBase Ca are a self-etching, self-adhesive, dual-cured resin luting cement and base/liner that is exclusively formulated for luting crowns, bridges, inlays, onlays and posts (prefabricated metal and non-metal/fiber posts, as well as cast posts) and basing/lining under restorations. TheraBase is a paste/paste, fluoride- and calcium-releasing, luting cement and base/liner which requires no etching, no priming or bonding of the prepared surfaces. TheraBase Ca is a paste/paste, calcium-releasing, luting cement and base/liner which requires no etching, no priming or bonding of the prepared surfaces. They are easy-to use, require only a short chair time, and produce a good bond to most dental materials. The cements are available in a Natural shade. They are radiopaque, allowing for easy identification on radiographs.

Technological Characteristics:

All components of TheraBase and TheraBase Ca are based upon industry standard chemistry. The chemical composition of TheraBase is the same as TheraCem. The chemical composition of TheraBase Ca is similar to TheraCem. The chemical composition of TheraBase and TheraBase Ca is similar to NuSmile BioCem. The chemical compositon of each product is summarized in the table below:

Chemical Composition	TheraCem (K161256)	NuSmile BioCem (K123265)	TheraBase	TheraBase Ca
Filler	Amorphous Silica & Portland Cement	Amorphous Silica	Amorphous Silica & Portland Cement	Amorphous Silica & Portland Cement
Resin composition	Methacrylate based	Methacrylate based	Methacrylate based	Methacrylate based
Polymerization Method	Dual cured	Dual cured	Dual cured	Dual cured
Method of Application	Bonding agent not required	Bonding agent not required	Bonding agent not required	Bonding agent not required
Ions Released	Calcium and fluoride	Calcium, phosphate, and fluoride	Calcium and fluoride	Calcium

Physical Mechanical Property	TheraCem (K161256)	NuSmile BioCem (K123265)	TheraBase	TheraBase Ca
Radiographic Appearance	Radiopaque	Radiopaque	Radiopaque	Radiopaque
Ions Released	Fluoride and calcium releasing	Fluoride and calcium releasing	Fluoride and calcium releasing	Calcium releasing
Delivery system	Dual-syringe	Dual-syringe	Dual-syringe	Dual-syringe

The difference in filler is TheraCem's, TheraBase's, and TheraBase Ca's additional use of Portland cement, an industry standard chemical, to facilitate calcium release and is substantially equivalent in performance to amorphous silica.

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510 (k) SUMMARY (continued)

Performance Data:

The following physical/mechanical properties of TheraBase and TheraBase Ca were tested:

Physical / Mechanical Property	TheraBase	TheraBase Ca
Bond Strength (Modified ISO 29022 and Gel-Cap method)	TheraBase is higher than or equivalent to 6.9 MPa, and bond to all the substrates.	TheraBase Ca is higher than or equivalent to 6.9 MPa, and bond to all the substrates.
Diametral Tensile Strength	TheraBase is greater than or equal to 32 MPa.	TheraBase Ca is greater than or equal to 32 MPa.
Film Thickness (ISO 4049:2009)	TheraBase is < 35 µm which meets the ISO 4049:2009 requirement of < 50 µm.	TheraBase Ca is < 35 µm which meets the ISO 4049:2009 requirement of < 50 µm.
Flexural Strength (ISO 4049:2009)	TheraBase is greater than the minimum flexural strength of 50 MPa.	TheraBase Ca is greater than the minimum flexural strength of 50 MPa.
Radiopacity (ISO 4049:2009)	TheraBase is greater than or equal to 2.0.	TheraBase Ca is greater than or equal to 2.0.
Working Time / Setting Time	TheraBase is greater than the minimum working time of 1 minute at room temperature (22±1°C) and is less than the maximum setting time of 5 minutes at 37±1°C.	TheraBase Ca is greater than the minimum working time of 1 minute at room temperature (22±1°C) and is less than the maximum setting time of 5 minutes at 37±1°C.
Compressive Strength	TheraBase is equivalent to or greater than 189 MPa.	TheraBase Ca is equivalent to or greater than 189 MPa.
Calcium Release	TheraBase releases calcium greater than or equal to 3.3 µg Ca/cm^2.	TheraBase Ca releases calcium greater than or equal to 3.3 µg Ca/cm^2.
Fluoride Release	TheraBase releases fluoride.	N/A, TheraBase Ca does not contain fluoride.

Biocompatibility:

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

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510 (k) SUMMARY (continued)

Conclusion:

It is concluded from review of the predicate device indications, chemical composition, biocompatibility, and physical properties that TheraBase and TheraBase Ca are substantially equivalent to the predicate devices.

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