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

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

July 29, 2016

Re: K161256
Trade/Device Name: Theracem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA,
Dated: May 2, 2016
Received: May 4, 2016

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,

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)*

K161256

Device Name
TheraCem

Indications for Use *(Describe)*

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)

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
Tel: 847-534-6143
Fax: 847-534-6143


Date Prepared: 02 May 2016

Trade Name: **TheraCem**
Common Name: Self-Adhesive Resin Cement
Product Code: EMA
Classification/Name: Dental Cement
**Class II per 21 CFR 872.3275**

**Predicate Devices:**

**TheraCem is substantially equivalent to:**

Primary Predicate: BisCem by Bisco, Inc. K082449
Reference Predicate: NuSmile Biocem by NuSmile, LTD / Pulpdent K123265

**Indications for Use:**

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)

510 (k) SUMMARY (continued)

The indications for use of TheraCem are the same as those for BisCem and NuSmile BioCem and are summarized in the table below:

| BisCem (K082449) | TheraCem | NuSmile BioCem (K123265) |
|---|---|---|
| • Luting metal crowns, bridges, inlay, and onlays including porcelain-fused-to-metal and composite-to-metal varieties<br>• Luting resin crowns, bridges, inlays, onlays, and veneers;<br>• Luting metal or non-metal/fiber posts;<br>• Luting orthodontic appliances;<br>• Luting porcelain inlays, onlays, crowns, and veneers (includes alumina and zirconia) | Use TheraCem to cement the following:<br>1. Metal crowns, bridges, inlays and onlays (includes porcelain-fused-to-metal and composite-to-metal)<br>2. Porcelain, Ceramic Crowns, inlays and onlays (includes alumina and zirconia)<br>3. Resin crowns, bridges, inlays and onlays (resin-based composite/composite-ceramic hybrid)<br>4. Metal (prefabricated or cast) and non-metal/fiber endodontic posts<br>5. Implant supported restorations<br>6. Orthodontic Appliances (brackets, bands) | 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. |

**Description of Applicant Device:**

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



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800-247-3368 or 847-534-6000
Fax: 847-891-5049
www.bisco.com

510 (k) SUMMARY (continued)

**Technological Characteristics:**

All components of TheraCem are based upon industry standard chemistry. The chemical composition of TheraCem is similar to BisCem and BioCem and is summarized in the table below:

| Chemical Composition | BisCem (K082449) | NuSmile BioCem (K123265) | TheraCem |
|---|---|---|---|
| **Filler** | Amorphous Silica | Amorphous Silica | Amorphous Silica & Portland Cement |
| **Resin composition** | Methacrylate based | Methacrylate based | Methacrylate based |
| **Polymerization Method** | Dual cured | Dual cured | Dual cured |
| **Method of Application** | Bonding agent not required | Bonding agent not required | Bonding agent not required |
| **Ions Released** | Fluoride | Calcium, phosphate, and fluoride | Calcium and fluoride |

| Physical Mechanical Property | BisCem (K082449) | NuSmile BioCem (K123265) | TheraCem |
|---|---|---|---|
| **Radiographic Appearance** | Radiopaque | Radiopaque | Radiopaque |
| **Ions Released** | Fluoride releasing | Fluoride and calcium releasing | Fluoride and calcium releasing |
| **Delivery system** | Dual-syringe | Dual-syringe | Dual-syringe |

The difference in filler is TheraCem's use of Portland cement, an industry standard chemical, to facilitate calcium release and is substantially equivalent in performance to amorphous silica. A reference predicate, BioCem (K123265), has been included to demonstrate substantial equivalence for calcium releasing.



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510 (k) SUMMARY (continued)

**Performance Data:**

The following physical/mechanical properties of TheraCem were tested:

| Physical / Mechanical Property | TheraCem |
|---|---|
| Bond Strength (Modified ISO 29022 and Gel-Cap method) | TheraCem is equivalent to the predicates. |
| Diametral Tensile Strength | TheraCem is equivalent to the predicates. |
| Film Thickness (ISO 4049:2009) | TheraCem meets the requirements of ISO 4049:2009 for Film Thickness. |
| Flexural Strength (ISO 4049:2009) | TheraCem meets the requirements of ISO 4049:2009 for Flexural Strength. |
| Radiopacity (ISO 4049:2009) | TheraCem meets the requirements of ISO 4049:2009 for Radiopacity. |
| Working Time / Setting Time | TheraCem is equivalent to the predicates. |
| Compressive Strength | TheraCem is equivalent to the predicates. |
| Calcium Release | TheraCem is equivalent to the predicates. |
| Fluoride Release | TheraCem is equivalent to the predicates. |

**Biocompatibility:**

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

**Conclusion:**

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