November 18, 2019

Bisco, Inc
Ryan Hobson
RA Product Registration Manager
1100 W Irving Park Rd
Schaumburg, Illinois 60193

Re: K182917
Trade/Device Name: FluoroCal
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: October 18, 2019
Received: October 24, 2019

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. 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 Srinivas Nandkumar, Ph.D.
Acting 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)*
K182917

Device Name
FluoroCal

Indications for Use *(Describe)*
1. Treats hypersensitive teeth
2. Treats exposed dentin and root sensitivity

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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K182917

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:	18 October 2019
Trade Name:	**FluoroCal**
Common Name:	5% Sodium Fluoride Varnish with Tri-Calcium Phosphate
Product Code:	LBH
Classification/Name:	Cavity Varnish **Class II per 21 CFR 872.3260**

Predicate Devices:

FluoroCal is substantially equivalent to:

Primary Predicate: Vanish Varnish, 5% Sodium Fluoride White Varnish by 3M ESPE Dental Products - K092141

Reference Predicate: MI Varnish, by GC America Inc. - K102808

Indications for Use:

1. Treats hypersensitive teeth
2. Treats exposed dentin and root sensitivity

510(k) SUMMARY (continued)

Indications for Use

The indications for use of FluoroCal are similar as those for the primary predicate and the reference predicate and are summarized in the table below:

Vanish Varnish White (K092141)	MI Varnish (K102808)	FluoroCal
• Treatment of hypersensitive teeth • Use on exposed dentin and root sensitivity • Under temporary restoratives and cements where post-operative sensitivity is of concern	MI Varnish is a fluoride varnish with Recaldent™ (CPP-ACP) that has a desensitizing action when applied to tooth surfaces. The application leaves a film of varnish on tooth and this may allow visual control and verification.	1. Treats hypersensitive teeth 2. Treats exposed dentin and root sensitivity

The only difference between FluoroCal and the primary predicate device is that FluoroCal is not indicated for use under temporary restoratives. Both of FluroCal's indications are identical to the first two indications of the primary predicate. Fluorocal's indications are similar to the reference predicate in that they both treat sensitization on tooth surfaces.

Description of Applicant Device:

FluoroCal is a fluoride & calcium releasing varnish with Tri-Calcium Phosphates (TCP) for application to enamel and dentin for the treatment of hypersensitive teeth. **FluoroCal** delivers targeted and sustained release of fluoride & calcium over 24 hours.[1] This varnish penetrates and seals dentin tubules, providing immediate relief of sensitivity. Available in Spearmint; sweetened with Xylitol.

1 As tested in deionized water.

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Schaumburg, IL 60193 U.S.A.
800-247-3368 or 847-534-6000
Fax: 847-891-5049
www.bisco.com

510(k) SUMMARY (continued)

Technological Characteristics:

All components of FluoroCal are based upon industry standard chemistry. The chemical composition of FluoroCal is similar to Vanish Varnish (K092141) and MI Varnish (K102808) summarized in the table below:

Chemical Composition	Vanish Varnish White (K092141)	MI Varnish (K102808)	FluoroCal
Rosin	Hydrogenated Rosins	Hydrogenated Rosins	Hydrogenated Rosins
Solvent	n-Hexanes, Ethanol	Ethoxyethanol; Ethanol	Triethylene glycol; Ethanol
Ion release	Fluoride, Calcium	Fluoride, Calcium	Fluoride, Calcium

Physical Mechanical Property	Vanish Varnish White (K092141)	MI Varnish (K102808)	FluoroCal
Fluoride Content	Meets requirements of ISO 17730:2014(E)	Meets requirements of ISO 17730:2014(E)	Meets requirements of ISO 17730:2014(E)
Consistency	Non-clumping	Non-clumping	Non-clumping
pH	6	6.2	6.4
Calcium Release	Releases Calcium	Releases Calcium	Releases Calcium
Fluoride Release	Releases Fluoride	Releases Fluoride	Releases Fluoride
Tubule Occlusion	Occludes dentin tubules	Occludes dentin tubules	Occludes dentin tubules
Delivery system	Foil pouch	Blister package	Blister package

Performance Data:

The following physical/mechanical properties of FluoroCal were tested:

Physical / Mechanical Property	FluoroCal
Fluoride Content (ISO 17730:2014(E)	FluoroCal meets the requirements of the standard and is equivalent to the predicates.
Consitency (ANS/ADA Spec #8 4.3.2)	FluoroCal is equivalent to the predicates.
pH	FluoroCal is equivalent to the predicates.
Calcium Release	FluoroCal is equivalent to the predicates.
Fluoride Release	FluoroCal is equivalent to the predicates.
SEM Tubule Occlusion	FluoroCal 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 FluoroCal. It is concluded from the safety evaluation and the results of the Oral Toxicity testing that FluoroCal meets the requirements of the testing.

Conclusion:

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

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