July 11, 2025

Bisco, Inc
Jessica Bernstein
Global Regulatory Affairs Manager
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K250156
Trade/Device Name: Choice 2 DC
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: March 21, 2025
Received: January 25, 2025

Dear Jessica Bernstein:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250156

Device Name

Choice 2 DC

Indications for Use *(Describe)*

Choice 2 DC is a dual-cured, resin luting/veneering cement. The indications for use are to cement:

1. Indirect restorations (i.e. crowns, fixed prostheses (bridges), inlay, onlays
2. Endodontic posts
3. Cement-retained implant restorations/abutments (i.e. screws and crowns)
4. Veneers

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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510(k) #: K250156

510(k) Summary

Prepared on: 2025-07-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Bisco, Inc
Applicant Address	1100 West Irving Park Road Schaumburg IL 60193 United States
Applicant Contact Telephone	847-534-6034
Applicant Contact	Ms. Jessica Bernstein
Applicant Contact Email	jbernstein@bisco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Choice 2 DC
Common Name	Dental cement
Classification Name	Cement, Dental
Regulation Number	872.3275
Product Code(s)	EMA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K101787	Duo-Link Universal (cleared as DUOLINK II)	EMA

Device Description Summary

21 CFR 807.92(a)(4)

Choice 2 DC is a color stable dual-cured, resin luting/veneering cement that is specially formulated for the cementation of indirect restorations made from Glass Ceramic, Lithium Disilicate, Porcelain, Composite, Metal, or Zirconia.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Choice 2 DC is a dual-cured, resin luting/veneering cement. The indications for use are to cement:

1. Indirect restorations (i.e. crowns, fixed prostheses (bridges), inlay, onlays
2. Endodontic posts
3. Cement-retained implant restorations/abutments (i.e. screws and crowns)
4. Veneers

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of Choice 2 DC are the similar to those for the predicate and reference devices. Minor differences in the indications for use do not change the intended use.

Technological Comparison

21 CFR 807.92(a)(6)

Choice 2 DC has similar technological characteristics to the predicate device, Duo-Link Universal (K101787), and the reference device, Variolink Esthetic DC (K142389). All components of Choice 2 DC are based upon industry standard chemistry. The chemical composition of Choice 2 DC is similar to the predicate and reference devices. All three devices are dual-cured, paste / paste form, and radiopaque. All

three require the use of a dental adhesive and are available in a dual-syringe. The reference device is included due to the similar self-cure initiator system incorporated into the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Choice 2 DC, the predicate device, and the reference device were tested according to ISO 4049:2019. The tests conducted from ISO 4049:2019 were film thickness, working time, setting time, flexural strength, water sorption, water solubility, shade/color stability, and radiopacity. Additionally shear bond strength testing per ISO 29022:2013 was also conducted.

Biological safety of Choice 2 DC was assessed using ISO 7405:2018 and ISO 10993-1:2018 and found to be biocompatible.

Clinical testing is Not Applicable.

The nonclinical testing showed Choice 2 DC performed at least equal to the predicate and reference devices. In addition, Choice 2 DC met the requirements set forth in ISO 4049:2019. These results demonstrate that Choice 2 DC is as safe, as effective, and performs at least as well as the predicate and reference devices.