December 17, 2024

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

Re: K242816
Trade/Device Name: Quantium
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: September 12, 2024
Received: September 18, 2024

Dear Jessica Berstein:

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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*

K242816

Device Name

Quantium

Indications for Use *(Describe)*

- Direct anterior and posterior restorations
- Core build ups
- Splinting
- Indirect restorations including inlays, onlays, and 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) #: K242816

510(k) Summary

Prepared on: 2024-09-18

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	Quantium
Common Name	Tooth shade resin material
Classification Name	Material, Tooth Shade, Resin
Regulation Number	872.3690
Product Code(s)	EBF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202063	TrusFIL Universal Composite Restorative	EBF

Device Description Summary

21 CFR 807.92(a)(4)

Quantium is a light-cured, radiopaque, universal composite. Quantium is designed to blend with the tooth structure when used alone or in the layering technique.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

- Direct anterior and posterior restorations
- Core build ups
- Splinting
- Indirect restorations including inlays, onlays, and veneers

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are similar. The additional text in the first indication of the predicate does not change the intended use; both the devices are indicated for direct anterior and posterior restorations.

Technological Comparison

21 CFR 807.92(a)(6)

Both Quantium and the predicate TrusFIL are methacrylate-based, radiopaque, light-cure pastes. Both also require the use of a dental adhesive and are available in a syringe and unit-dose capsule. The chemical composition of Quantium is similar to TrusFIL. All components of Quantium are based upon industry standard chemistry. The difference in filler is Quantium's use of Ytterbium Fluoride, an industry standard filler, and is substantially equivalent in performance to TrusFIL's fillers.

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

Nonclinical testing of Quantium and the predicate device was selected from the FDA Guidance Document, Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff, issued October 2005. Sensitivity to light, depth of cure, flexural strength, water sorption, water solubility, shade/color stability, and radiopacity were tested according to ISO 4049:2019. Additionally, compressive strength, flexural modulus, and hardness after cure were also tested.

Clinical testing is Not Applicable.

The nonclinical tests performed on Quantium and the predicate device showed Quantium performed equal to or better than the predicate. In addition, both devices meet the requirements set forth in ISO 4049:2019. These results demonstrate that Quantium is as safe, as effective, and performs as well as the predicate.