



November 7, 2025

Premier Dental Products Company  
% Prithul Bom  
Most Responsible Person  
Regulatory Technology Services, LLC  
1000 Westgate Drive,  
Suite 510k  
Saint Paul, Minnesota 55114

Re: K253513

Trade/Device Name: MultiMatch Flow Chameleon AntiMicrobial Composite  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth shade resin material  
Regulatory Class: Class II  
Product Code: EBF, DYH, EBC  
Dated: November 5, 2025  
Received: November 6, 2025

Dear Prithul Bom:

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](mailto: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  
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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253513

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Please provide the device trade name(s).

?

MultiMatch Flow Chameleon AntiMicrobial Composite

Please provide your Indications for Use below.

?

- Direct restorations in all cavity classes (I-V)
- Base / liner under direct restoration
- Veneering of discolored anterior teeth
- Splinting of mobile teeth
- Extended pit and fissure sealing in molars and premolars
- Repair of composite/ceramic veneers
- Retention of thermoplastic aligners

The addition of anti-microbial particles to MultiMatch Flow Chameleon AntiMicrobial Composite reduces demineralization and the total amount of bacteria at the material surface, which is part of the caries-formation process.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

**510(k) SUMMARY**  
**Premier Dental's MultiMatch Universal Chameleon Restorative Composite**

**1. Submitter Information**

Premier Dental Products Company  
1710 Romano Drive  
Plymouth Meeting, PA 19462

Contact Person: Jessica Huang, Sr. Director of Quality/Regulatory  
Phone: 610-239-6069  
Facsimile: 610-239-6171

Date Prepared: November 3, 2025

**2. Name of Device**

Proprietary Name: MultiMatch Flow Chameleon AntiMicrobial Composite  
Common Name: Tooth Shade Resin Material  
Review Panel: Division of Dental and ENT Devices (DHT1B)  
Classification Name: Material, Tooth Shade, Resin  
Regulatory Class: 2  
Product Code: EBF  
Regulation Number: 21 CFR 8872.3690

**3. Predicate Devices**

Product	Applicant	510(k) No.	Product Code	Predicate
Infinix™ Flowable Composite	Nobio Ltd.	K201010	EBF	Primary
Flowtain	Reliance Orthodontic Products, Inc.	K083051	DYH	Reference

**4. Device Description**

Premier's MultiMatch Flow Chameleon AntiMicrobial Composite is a low viscosity, light-cured, radiopaque, flowable nano-hybrid composite. It is for use in direct Class I-V restorations as a base liner, indirect restorations, and for retention of clear aligners. The restorative has an antimicrobial additive which reduces demineralization and total amount of bacteria at the material surface. The restorative is available in one chameleon shade to fit a variety of tooth-colored shades.

**5. Indications for Use**



Premier's MultiMatch Flow Chameleon Antimicrobial Composite has the following indications for use:

- Direct restorations in all cavity classes (I-V)
- Base / liner under direct restoration
- Veneering of discolored anterior teeth
- Splinting of mobile teeth
- Extended pit and fissure sealing in molars and premolars
- Repair of composite/ceramic veneers
- Retention of thermoplastic aligners

The addition of anti-microbial particles to MultiMatch Flow Chameleon AntiMicrobial Composite reduces demineralization and the total amount of bacteria at the material surface, which is part of the caries-formation process.

#### 6. Summary of Technological Characteristics

Premier's MultiMatch Flow Chameleon AntiMicrobial Composite is substantially equivalent to the predicate device, Nobio's Infinix Flowable Composite (K201010), in terms of indications for use, composition, physical properties, and technological characteristics. Both the subject device and the predicate device are methacrylate-based light curing resin systems containing filler particles to form a flowable paste which can be applied into a restoration site directly. The composite is designed to have high mechanical strength and durability while maintaining excellent handling and esthetic characteristics.

Premier's MultiMatch Flow formulation differs from the predicate device as it exhibits chameleon effect, which enables MultiMatch Flow to match all 16 VITA shades with only one universal shade. In contrast, the predicated device, Infinix Flowable (K201010) offers 3 shades in A1, A2, and A3.

The subject device, Premier's MultiMatch Flow, and the predicated device, Infinix Flowable (K201010), both contain silica-based antimicrobial particles. Both subject and predicated devices have the indication of reducing demineralization. Premier's MultiMatch Flow also has an indication for reducing the total bacteria amount on material surface.

A table comparing the key features of the subject and predicate devices is provided below.

	<b>Subject Device: MultiMatch Flow Chameleon AntiMicrobial Composite</b>	<b>Predicated Device: Nobio Infinix Flowable Composite (K201010)</b>	<b>Reference device: Flowtain (K083051)</b>
<b>Indications for Use</b>	<ul style="list-style-type: none"> <li>• Direct restorations in all cavity classes (I-V)</li> <li>• Base / liner under direct restoration</li> <li>• Veneering of discolored anterior teeth</li> </ul>	<ul style="list-style-type: none"> <li>•Restorations in the posterior region (Class I and II)</li> <li>•Anterior restorations (Class III, IV)</li> </ul>	<ul style="list-style-type: none"> <li>• For the bonding of lingual retainers and splinting materials, creation of archwire stops and indirect</li> </ul>

	<ul style="list-style-type: none"> <li>• Splinting of mobile teeth</li> <li>• Extended pit and fissure sealing in molars and premolars</li> <li>• Repair of composite/ceramic veneers</li> <li>• Retention of thermoplastic aligners</li> </ul> <p>The addition of anti-microbial particles to MultiMatch Flow Chameleon AntiMicrobial Composite reduces demineralization and the total amount of bacteria at the material surface, which is part of the caries-formation process.</p>	<ul style="list-style-type: none"> <li>• Class V restorations (cervical caries, root erosion, wedge-shaped defects)</li> <li>• Veneering of discolored anterior teeth</li> <li>• Splinting of mobile teeth</li> <li>• Extended fissure sealing in molars and premolars</li> <li>• Repair of composite/ceramic veneers</li> </ul> <p>The addition of the QASi particles to the Infinix Universal Composite reduces demineralization, which is part of the caries-formation process.</p>	<p>bonding of orthodontic brackets.</p> <ul style="list-style-type: none"> <li>• Can be used for the retention of thermoplastic aligners.</li> <li>• Flowtain LV intended to be used for indirect bonding of orthodontic brackets and bonding to enamel surfaces.</li> </ul>
Classification Name	Material, Tooth Shade, Resin	Material, Tooth Shade, Resin	Adhesive, bracket and tooth conditioner, resin
Class	2	2	2
Product Code	EBF	EBF	DYH
<b>Target Population</b>	Any age patient requiring restoration or repair of teeth.	Any age patient requiring restoration or repair of teeth.	Any age patient requiring restoration or repair of teeth.
<b>Method of Use</b>	Bonding agent is applied and the composite is layered on and light-cured for each layer.	Bonding agent is applied and the composite is layered on and light-cured for each layer.	Bonding agent is applied and the composite is layered on and light-cured for each layer.
Curing Mechanism	Light Cure	Light Cure	Light Cure
Composition	UV Curable resins, Glass Filler, Photo-initiator, Co-initiator, Silica-based antimicrobial particles and Pigments	UV Curable resins, Glass Filler, Photo-initiator, Co-initiator, Silica-based antimicrobial particles and Pigments	UV Curable resins, Photo-initiator, Glass filler

<b>Technological Characteristics</b>	Performance of the device meets the requirements of ISO 4049:2019, ISO 9917:2007, ISO 29022:2013, and ISO 17304:2013	Performance of the device meets the requirements of ISO 4049:2019, ISO 9917:2007, ISO 29022:2013, ISO 17304:2013	Performance of the device meets the requirements of ISO 29022:2013
<b>Sterility</b>	Non-sterile	Non-sterile	Non-sterile
<b>Shade</b>	Single shade to match all 16 Vita Shades	3 shades (A1, A2, A3)	-
<b>Biocompatibility</b>	Biocompatible	Biocompatible	Biocompatible
<b>Antimicrobial Property</b>	Reduces demineralization, Reduces total bacterial amount at material surface	Reduces demineralization	-
<b>Delivery System</b>	Syringe and Unit Dose Capsules	Syringe and Unit Dose Capsules	Syringe

## 7. Non-Clinical Testing

### a. Performance

Performance tests for Premier's MultiMatch Flow Chameleon AntiMicrobial Composite were conducted following on the FDA's recognized consensus standards for dental composites. Bench tests, including flexural strength, compression strength, water sorption, water solubility, cure time, cure depth, shear bond strength, polymerization conversion and shrinkage, radiopacity, and color, were performed on Premier's MultiMatch Flow device against the predicate device Nobio Infinix Flowable Composite (K201010). The subject device passed all evaluations, demonstrated physical characteristics equal or better than the predicated device (K201010). The testing results confirmed Premier's MultiMatch Flow meets its intended physical and performance requirements.

### b. Biocompatibility

To demonstrate the overall biological safety of Premier's MultiMatch Flow Chameleon AntiMicrobial Composite, cytotoxicity, sensitivity, irritation, acute systemic toxicity, and genotoxicity tests were performed following ISO 10993 standards. MultiMatch Flow showed no observed cytotoxicity, no skin sensitivity, no mucosa irritation, no systemic toxic reaction, and no genotoxicity. Based on these results, MultiMatch Flow is biocompatible.

### c. Antimicrobial Testing

*In Vitro* Bacterial Biomarkers and *In Vitro* Demineralization tests were performed to support the indications of reducing demineralization and the total amount of bacteria at the material surface, which is part of the caries-formation process. The *in vitro* studies showed that Premier's MultiMatch Flow significantly reduced the total amount of bacteria at the material

surface and reduced the demineralization volume versus the predicated Nobio Infinix Flowable Composite (K201010).

Note- *In vitro* multispecies biofilm studies have shown MultiMatch™ Flow Chameleon Antimicrobial Composite's ability to act on the following organisms<sup>1</sup>.

- *Streptococcus mutans (GP)*
- *Streptococcus oralis (GP)*
- *Actinomyces naeslundii (GP)*
- *Veillonella dispar (GN)*
- *Fusobacterium nucleatum (GN)*
- *Candida albicans (Fungus)*

1. Data on file

## 8. Conclusions

Premier's MultiMatch Flow Chameleon AntiMicrobial Composite is as safe and effective as the predicate device. Premier's MultiMatch Flow has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between Premier's MultiMatch Flow and its predicate devices raise no new issues of safety or effectiveness. Non-Clinical Performance data demonstrate that Premier's MultiMatch Flow is as safe and effective as predicated device of Infinix Flowable (K201010). Thus, Premier's MultiMatch Flow is substantially equivalent.