July 19, 2024

Formlabs Ohio, Inc.
Paige Johnson
Senior Regulatory Affairs Specialist
27800 Lemoyne Rd
Millbury, Ohio 43447

Re: K240538
Trade/Device Name: Premium Teeth Resin
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, PZY
Dated: June 20, 2024
Received: June 20, 2024

Dear Paige Johnson:

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.

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 Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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)*

K240538

Device Name

Premium Teeth Resin

Indications for Use *(Describe)*

Premium Teeth Resin, when utilized to print 3D printed dental appliances such as denture teeth for complete and partial removable dentures, try-in dentures, provisional full arch implant-supported restoration and provisional restorations such as temporary crowns and bridges, inlays, onlays and veneers, is indicated to replace or restore missing tooth structures or missing teeth.

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) #: K240538

510(k) Summary

Prepared on: 2024-06-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Formlabs Ohio, Inc.
Applicant Address	27800 Lemoyne Rd Millbury OH 43447 United States
Applicant Contact Telephone	781-336-8303
Applicant Contact	Ms. Paige Johnson
Applicant Contact Email	paige.johnson@formlabs.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Premium Teeth Resin
Common Name	Temporary crown and bridge resin
Classification Name	Crown And Bridge, Temporary, Resin
Regulation Number	872.3770
Product Code(s)	EBG, PZY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193553	VarseoSmile Temp	EBG

Device Description Summary

21 CFR 807.92(a)(4)

Formlabs Premium Teeth Resin is a light-curable polymer-based resin designed for the fabrication of 3D printed dental appliances, such as denture teeth for complete and partial removable dentures, try-in dentures, provisional full arch implant-supported restoration, and provisional restorations including temporary crowns and bridges, inlays, onlays and veneers. Formlabs Premium Teeth Resin is used to fabricate patient-specific dental appliances in a stereolithographic (SLA) 3D printer using layer-by-layer additive manufacturing.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Premium Teeth Resin, when utilized to print 3D printed dental appliances such as denture teeth for complete and partial removable dentures, try-in dentures, provisional full arch implant-supported restoration and provisional restorations such as temporary crowns and bridges, inlays, onlays and veneers, is indicated to replace or restore missing tooth structures or missing teeth.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Formlabs Ohio, Inc., submits that the Subject device, Premium Teeth Resin, is Substantially Equivalent to the legally marketed Predicate device, VarseoSmile Temp (K193553).

Indications for Use:
The Subject and Predicate are Substantially Equivalent, as they are both indicated for the fabrication of temporary dental restorations using additive manufacturing and light-curing equipment, or in other words, to replace or restore missing tooth structures or missing teeth. The Indications for Use of the Subject device goes into more detail regarding the specific temporary dental restorations which it is indicated (temporary crowns and bridges, inlays, onlays, and veneers), however, the Predicate device mentions these exact temporary

restorations in its labeled Intended Use. Additionally, the Subject Device is indicated for use in denture teeth applications for complete and partial removable dentures, try-in dentures, and provisional full arch implant-supported restorations. These applications fall under the product code "PZY" (Additively Manufactured, Preformed, Resin Denture Tooth) and are 510(k) exempt, therefore out of the scope of this submission. Given the similarities of each device's Intended Use, these minor discrepancies within their Indications For Use are negligible.

Technological Comparison 21 CFR 807.92(a)(6)

Formlabs Ohio, Inc., submits that the Subject device, Premium Teeth Resin, is Substantially Equivalent to the legally marketed Predicate device, VarseoSmile Temp (K193553) with regard to Technological Characteristics. Both devices are intended for use by dental and orthodontic professionals for the fabrication of temporary dental restorations using additive manufacturing. Both the Subject and Predicate devices are methacrylate polymer resins with a photo initiator, inhibitor and pigments.

Material Shades:
The Subject and Predicate are Substantially Equivalent, offering common shades in the VITA Shade Guide. The Subject device offers an additional option, a common Bleach shade developed by Formlabs. This minor difference in material shades does not raise questions of safety and effectiveness.

Biocompatibility:
The Subject and Predicate are Substantially Equivalent. The same biological endpoints were evaluated for both devices: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, and Genotoxicity. Both the Subject and Predicate devices passed these biological endpoint tests and can be defined as biocompatible when used as intended.

Per the results of our comparative analyses and the decision-making flowchart in Appendix A of the FDA Guidance "Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", it can be concluded that the Subject and Predicate devices demonstrate Substantial Equivalence.

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

To test the performance of mechanical properties of the Subject and Predicate, both Formlabs and BEGO tested to applicable standards ISO 4049:2019, Dentistry – Polymer-based restorative materials and ISO:10477:2018, Dentistry – Polymer-based crown and veneering materials. While there are no precise performance results available for the Predicate device, BEGO has indicated in their labeling and technical documents available online, that their device has met the acceptable ranges listed in the aforementioned standards for polymer-based crown and veneering materials. The performance results for the Subject device also fell within the acceptable ranges for polymer-based crown and veneering materials.

Testing for accuracy and scan analysis of 3D printed samples of the device was conducted per the FDA Guidance Document "Technical Considerations for Additively Manufactured Devices."

The testing demonstrated substantial equivalence.