June 25, 2025

Prismatik Dentalcraft, Inc.
Jiahe Li
Regulatory Affairs Specialist, Principal
2144 Michelson Drive
Irvine, California 92612

Re: K250302
Trade/Device Name: Flexible Partial Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: January 31, 2025
Received: February 3, 2025

Dear Jiahe Li:

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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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)*

K250302

Device Name

Flexible Partial Resin

Indications for Use *(Describe)*

Flexible Partial Resin is indicated for the fabrication of dental appliances such as dental plates, bite plates, partial denture frame-works and clasps.

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.

K250302

510(k) Summary

Date Prepared: June 19, 2025

Contact Details (21 CFR 807.92(a)(1))

Applicant Name: Prismatik Dentalcraft, Inc.

Applicant Address: 2144 Michelson Drive Irvine CA 92612 United States

Applicant Contact Telephone: 949-222-3516

Applicant Contact: Jiahe Li, Regulatory Affairs Specialist, Principal

Applicant Contact Email: jiahe.li@glidewelldental.com

Secondary Contact: So Hyun Park, Regulatory Affairs Manager

Secondary Contact Email: so.park@glidewelldental.com

Secondary Contact Phone: 949-863-5479

Device Name (21 CFR 807.92(a)(2))

Device Trade Name: Flexible Partial Resin

Common Name: Denture Base Resin

Classification Name: Denture relining, repairing, or rebasing resin

Regulation Number: 872.3760

Product Code: EBI

Legally Marketed Predicate Device (21 CFR 807.92(a)(3))

Predicate 510(k) #: K213994 (Primary predicate)

Predicate Trade Name: Flexible Block

Product Code: EBI, MQC

Reference 510(k) #: K223798

Reference Device Trade Name: Glidewell TuffSplint™ Appliance Resin

Product Code: MQC, KMY

Device Description Summary (21 CFR 807.92(a)(4))

The subject device, Flexible Partial Resin, is a light-cured polymerizable resin for the fabrication of partial removable denture bases made in dental laboratories. The resin can be used in DLP printers utilizing a wavelength of 385nm and will be offered in G1 (standard pink), G3 (medium pink), and G4 (dark pink) shades formulated to match gingival tissue. The final medical device is a custom fitted appliance that is compliant to the dental professional's diagnosis and prescription.

Intended Use/Indications for Use (21 CFR 807.92(a)(5))

Flexible Partial Resin is indicated for the fabrication of dental appliances such as dental plates, bite plates, partial denture frame-works and clasps.

Indications for Use Comparison (21 CFR 807.92(a)(5))

The indications for use are similar between the subject device, Flexible Partial Resin, and the predicate device, Flexible Block (K213994), as both devices are indicated for fabricating dental appliances such as dental plates, bite plates, partial denture frame-works and clasps.

The only difference is that the predicate device, Flexible Block, has additional indications for fabricating personal trays, appliances, occlusal splints and night guards. The difference does not constitute a new intended use for the subject device, Flexible Partial Resin, however, as the subject device's indications for making dental plates, bite plates, partial denture frame-works and clasps are included as a subset of the indications of the predicate device, Flexible Block (K213994).

Technological Comparison (21 CFR 807.92(a)(6))

The subject device, Flexible Partial Resin, is substantially equivalent to the predicate device, Flexible Block (K213994), in technological characteristics, including technical specifications, material and principles of operation.

A comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of the subject device, Flexible Partial Resin, and the predicate device, Flexible Block (K213994), is outlined in the table below.

Attributes		Subject Device	Main Predicate Device	Reference Device	Comparison
Device Name		Flexible Partial Resin	Flexible Block	Glidewell TuffSplint™ Appliance Resin	N/A
510(k)		(K050302)	(K213994)	(K223798)	N/A
Regulation		21 CFR 872. 3760	21 CFR 872. 3760	N/A	Same
Product Code		EBI	EBI, MQC	MQC, KMY	Additional product MQC for the predicate device.
Classification		Class II	Class II	Unclassified	Same
Manufacturer		Prismatik Dentalcraft, Inc.	Shandong Huge Dental Material Corporation	Prismatik Dentalcraft, Inc.	N/A
Intended Use/ Indications for Use		Flexible Partial Resin is indicated for the fabrication of dental appliances such as dental plates, bite plates, partial denture frame-works and clasps.	Intended for making dental plates, bite plates, frame-works, clasps, personal trays, appliances, occlusal splints and night guards.	Glidewell TuffSplint™ Appliance Resin is indicated for the fabrication of orthodontic and dental appliances such as bite planes, mouthguards, nightguards, splints and repositioners.	Same except that the predicate device included additional indications for making personal trays, appliances, occlusal splints and night guards.
Prescription Device		Yes	Yes	Yes	Same
Design Characteristic	Material Composition	Methacrylate/dimethacrylate- based resin with photo-initiator, stabilizer, fillers and pigments.	Polyamide	Light cured methacrylate based resin.	Similar. The different material composition does not affect the safety and effectiveness of the device
	Principle of Operation	Material for making removable dental appliances fitted to a patient's oral anatomy using CAD/CAM method. The finished appliances are 3D-printed using compatible DLP printer.	Material for making removable dental appliances fitted to a patient's oral anatomy using CAD/CAM method. The finished appliances are milled from pre-manufactured milling blocks.	Material for making removable dental appliances fitted to a patient's oral anatomy using CAD/CAM method. The finished appliances are 3D-printed using compatible DLP printer.	Similar. The only difference is in the manufacturing method of the finished appliances. For the subject device the appliances are 3D-printed, while for the predicate device the appliances are milled from pre-manufactured milling blocks.

Attributes		Subject Device	Main Predicate Device	Reference Device	Comparison
	Performance Testing	Flexural Strength (ASTM D790) Flexural Modulus (ASTM D790) Tensile Strength (ASTM D638) Elongation at Break (ASTM D638) Impact Strength (ASTM D256) Water Absorption (ASTM D570)	Flexural Strength (ASTM D790) Flexural Modulus (ASTM D790) Tensile Strength (ASTM D638) Elongation at Break (ASTM D638) Impact Strength (ASTM D256) Water Absorption (ASTM D570)	Flexural Strength (ISO 20795-2) Flexural Modulus (ISO 20795-2) Tensile Strength (ASTM D638) Tensile Modulus (ASTM D638) Elongation at Break (ASTM D638) Water Sorption (ISO 20795-2) Water Solubility (ISO 20795-2)	The subject device met the same performance criteria as the predicate device for all the performance tests. The reference device tested water sorption and solubility the ISO 20795-2:2013 (Same testing method as ISO 20795-1:2013).
	Sterility	Non-sterile	Non-sterile	Non-sterile	Same
	Biocompatibility	Biocompatible per testing results for all applicable end points per ISO 10993-1:2018.	Biocompatible per testing results for all applicable end points per ISO 10993-1:2018 .	Biocompatible per testing results according to ISO 10993-1:2018	Same

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

Performance Testing

Non-clinical data submitted for demonstrating substantial equivalence between the subject device, Flexible Partial Resin, and the predicate device, Flexible Block (K213994), include Flexural Strength and Flexural Modulus (ASTM D790-17), Tensile Strength (ASTM D638-22), Elongation at Break (ASTM D638-22), Impact Strength (ASTM D256-23e1), and Water Absorption (ASTM D570-22). The subject device, Flexible Partial Resin, was tested in comparison against the predicate device, Flexible Block (K213994), for each of the physical properties according to the test methods outlined in the corresponding ASTM standard.

In addition, printing accuracy test was performed to validate that the physical output of the additive manufacturing system and procedure for Flexible Partial Resin meet design input dimensions within the pre-specified tolerance. The samples were printed at 0°, 45° and 90° angle to validate that the hard resin printed at different print direction within the build space relative to the device orientation and at different build plate locations meet the same performance criteria. The results met the pre-specified acceptance criteria and demonstrated that the subject device, Flexible Partial Resin, can be reliably fabricated at different print directions within the build space and at different build plate locations using the additive manufacturing system and procedure.

The test results of Flexural Strength and Flexural Modulus (ASTM D790-17), Tensile Strength (ASTM D638-22), Elongation at Break (ASTM D638-22), Impact Strength (ASTM D256-23e1), and Water Absorption (ASTM-D570-22) showed that the subject device, Flexible Partial Resin, met the same acceptance criteria of the predicate device, Flexible Block (K213994), for all the

physical property tests. Meanwhile, the printing accuracy and orientation validation showed that the subject device can be reliably fabricated at different print directions within the build space and at different build plate locations using the additive manufacturing system and procedure. The test results were used to address questions related to substantial equivalence between the subject device, Flexible Partial Resin, and the predicate device, Flexible Block (K213994). The results from the non-clinical tests support that the subject device, Flexible Partial Resin, meets the same performance criteria and is as safe and effective as the predicate device, Flexible Block (K213994).

Water sorption and solubility data from the reference device, Glidewell TuffSplint™ Appliance Resin (K223798), which has similar formulation as Flexible Partial Resin, was leveraged to support that the water sorption and solubility of Flexible Partial Resin meet the requirements of ISO 20795-1:2013. Additionally, the validated packaging system of the reference device was cited to justify the use of the same packaging system for Flexible Partial Resin.

Biocompatibility

The subject device, Flexible Partial Resin, was evaluated in accordance with ISO 10993-1:2018. The biocompatibility data of the reference device, Glidewell TuffSplint™ Appliance Resin (K223798), was leveraged in evaluating the biocompatibility profile of the subject device. Based on the biological risk assessment and biocompatibility testing results, it was determined that there is no biocompatibility concern for the subject device, Flexible Partial Resin.

The test results were used to address questions related to substantial equivalence between the subject device, Flexible Partial Resin, and the predicate device, Flexible Block (K213994).