August 27, 2026

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

Re: K261802
Trade/Device Name: Glidewell™ Denture Base Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: May 29, 2026
Received: June 1, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Bobak Shirmohammadi -S

For 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.	K261802

Please provide the device trade name(s).

Glidewell™ Denture Base Resin

Please provide your Indications for Use below.

Glidewell™ Denture Base Resin is a light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment. Glidewell™ Denture Base Resin is indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

PRISMATIK DENTALCRAFT, INC.

510(k) Summary K261802

Date Prepared: May 26, 2026

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: Jiahe Li, Regulatory Affairs Specialist, Principal

Applicant Contact Email: jiahe.li@glidewelldental.com

Applicant Contact Telephone: 949-222-3516

Secondary Contact: So Hyun Park, Regulatory Affairs Manager, Senior

Secondary Contact Email: so.park@glidewelldental.com

Secondary Contact Phone: 949-535-3038

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

Device Trade Name: Glidewell™ Denture Base 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) #: K213765

Predicate Trade Name: Glidewell™ 3DP Denture Base Resin

Product Code: EBI

Reference 510(k) #: K241493

Reference Device Trade Name: Glidewell™ 3DP Denture Base Resin

Product Code: EBI

PRISMATIK DENTALCRAFT, INC.

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

Glidewell™ Denture Base Resin is a light-curable polymerizable resin with improved impact resistance, designed for fabricating and repairing full and partial removable dentures and baseplates. The resin is compatible with DLP printers utilizing wavelengths of 385 nm and is offered in three shades, G1 (light pink), G3 (medium pink) and G4 (dark pink).

Glidewell™ Denture Base Resin is a light-cured methacrylic material with photo initiators that form a polymer during 3D printing. Glidewell™ Denture Base Resin is printed using digital light processing (DLP). The DLP printer and resin are optimized to each other in order to achieve complete and precise printed parts. The light source is provided by the DLP printer (385nm wavelength), and the post-curing light box polymerizes the resin which forms a hardened denture base. Once cured, Glidewell™ Denture Base Resin exhibits mechanical properties that meet the performance criteria outlined in the FDA-recognized consensus standard ISO 20795-1:2013 — *Dentistry – Base Polymers – Part 1: Denture Base Polymers*. This includes compliance with requirements for flexural strength, flexural modulus, water sorption, and water solubility for Type 4 (light-activated materials), as well as fracture toughness for materials with enhanced impact resistance.

The subject device, Glidewell™ Denture Base Resin, contains the same antimicrobial agent, SelectedSilver® Zr2K (medical grade silver sodium hydrogen zirconium phosphate), as the predicate device, Glidewell™ 3DP Denture Base Resin (K213765 and K241493). Silver containing fillers such as the silver sodium hydrogen zirconium phosphate have been known to exhibit antimicrobial action against bacteria and fungi. *In vitro* studies on the subject device, Glidewell™ Denture Base Resin, demonstrated a reduction in the following microorganisms:

Microorganisms Susceptible to Glidewell™ 3DP Denture Base Resin
Streptococcus mutans
Streptococcus mitis
Staphylococcus aureus
Escherichia coli
Klebsiella pneumonia
Candida albicans
Candida glabrata
Candida tropicalis
MRSA (Methicillin Resistant *Staphylococcus aureus*)
VRE (Vancomycin Resistant *Enterococcus*)

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

Glidewell™ Denture Base Resin is a light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment. Glidewell™ Denture Base Resin is indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates.

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

The subject device, Glidewell™ Denture Base Resin, has the same indications for use, as the predicate device, Glidewell™ 3DP Denture Base Resin (K213765).

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

The subject device, Glidewell™ Denture Base Resin, is substantially equivalent to the predicate device, Glidewell™ 3DP Denture Base Resin (K213765), 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, Glidewell™ Denture Base Resin, and the predicate device, Glidewell™ 3DP Denture Base Resin (K213765 and K241493), is outlined in the table below.

Attributes		Subject Device	Primary Predicate Device	Reference Device	Comparison
Device Name		Glidewell™ Denture Base Resin	Glidewell™ 3DP Denture Base Resin	Glidewell™ 3DP Denture Base Resin	N/A
510(k)		TBD	(K213765)	(K241493)	N/A
Regulation		21 CFR 872. 3760	21 CFR 872. 3760	21 CFR 872. 3760	Same
Product Code		EBI	EBI	EBI	Same
Classification		Class II	Class II	Class II	Same
Manufacturer		Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Intended Use/ Indications for Use		Glidewell™ Denture Base Resin is a light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment. Glidewell™ Denture Base Resin is indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates.	Glidewell™ 3DP Denture Base Resin is a light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment. Glidewell™ 3DP Denture Base Resin is indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates.	Glidewell™ 3DP Denture Base Resin is a light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment. Glidewell™ 3DP Denture Base Resin is indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates.	Same except for the device name.
Prescription Device		Yes	Yes	Yes	Same
Design Characteristic	Material Composition	Methacrylate/dimethacrylate- based resin with photo-initiator, stabilizer, fillers and pigments. Contains silver sodium hydrogen zirconium phosphate as the antimicrobial agent.	Methacrylate/dimethacrylate- based resin with photo-initiator, stabilizer, fillers and pigments. Contains silver sodium hydrogen zirconium phosphate.	Methacrylate/dimethacrylate- based resin with photo-initiator, stabilizer, fillers and pigments. Contains silver sodium hydrogen zirconium phosphate as the antimicrobial agent.	Similar. The different material composition does not affect the safety and effectiveness of the device.
	Principle of Operation	Light-cured denture base resin 3D printed using digital light processing (DLP) technology, which involves the light-mediated conversion of a liquid resin containing monomer and oligomer photopolymers to a	Light-cured denture base resin 3D printed using digital light processing (DLP) technology, which involves the light-mediated conversion of a liquid resin containing monomer and oligomer photopolymers to a	Light-cured denture base resin 3D printed using digital light processing (DLP) technology, which involves the light-mediated conversion of a liquid resin containing monomer and oligomer photopolymers to a	Same

Attributes		Subject Device	Primary Predicate Device	Reference Device	Comparison
		solid object with the desired physical properties for removable dentures and baseplates.	solid object with the desired physical properties for removable dentures and baseplates.	solid object with the desired physical properties for removable dentures and baseplates.	
	Performance Testing	Flexural Strength (ISO 20795-1:2013) Flexural Modulus (ISO 20795-1:2013) Water Absorption (ISO 20795-1:2013) Water Solubility (ISO 20795-1:2013) Maximum Stress Intensity Factor (ISO 20795-1:2013) Total Fracture Work (ISO 20795-1:2013) *In vitro* antimicrobial testing conducted per ASTM E2180-24	Flexural Strength (ISO 20795-1:2013) Flexural Modulus (ISO 20795-1:2013) Water Absorption (ISO 20795-1:2013) Water Solubility (ISO 20795-1:2013)	Flexural Strength (ISO 20795-1:2013) Flexural Modulus (ISO 20795-1:2013) Water Absorption (ISO 20795-1:2013) Water Solubility (ISO 20795-1:2013) *In vitro* antimicrobial testing conducted per ASTM E2180-07	The subject device met the same physical performance criteria for Type 4 denture base polymer per ISO 20795-1:2013 as the predicate devices for all the performance tests. Subject device underwent similar *In vitro* antimicrobial testing as the reference device, with results documented in the respective Instructions for Use (IFUs). Subject device underwent additional Fracture Toughness tests to support the claim for material with improved impact resistance per 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))

Physical Property Tests

Non-clinical data submitted to demonstrate substantial equivalence between the subject device, Glidewell™ Denture Base Resin, and the predicate device, Glidewell™ 3DP Denture Base Resin (K213765), include Flexural Strength, Flexural Modulus, Water Absorption and Water Solubility. The tests were conducted in accordance with the ISO 20795-1:2013. The test results were

compared against the historical data of the predicate device submitted under K213765, and the results showed that the physical properties for subject device, Glidewell™ Denture Base Resin, met the same acceptance criteria of ISO 20795-1:2013 for type 4 light-activated materials as the predicate device, Glidewell™ 3DP Denture Base Resin (K213765). In addition, Fracture Toughness tests on Maximum Stress Intensity Factor and Total Fracture Work were performed to support the claim for material with improved impact resistance as described under ISO 20795-1:2013.

The results of the testing were used to address questions related to substantial equivalence based on differences in chemical composition between the subject device, Glidewell™ Denture Base Resin, and the predicate device, Glidewell™ 3DP Denture Base Resin (K213765).

In Vitro Antimicrobial Tests

In vitro studies were conducted to evaluate the activity of the incorporated antimicrobial agent, silver sodium hydrogen zirconium phosphate, in the subject device, Glidewell™ Denture Base Resin. These tests assessed the effectiveness of the device in reducing selected microorganisms upon surface contact and were performed in accordance with ASTM E2180-24, Standard test method for determining the activity of incorporated antimicrobial agent(s) in polymeric or hydrophobic materials. The tests conducted include the following:

- Antimicrobial contact tests per ASTM E2180-24 were conducted on the following selected microorganisms, each tested separately in an agar slurry:
    - *Streptococcus mutans*
    - *Streptococcus mitis*
    - *Staphylococcus aureus*
    - *Escherichia coli*
    - *Klebsiella pneumonia*
    - *Candida albicans*
    - *Candida glabrata*
    - *Candida tropicalis*
    - MRSA (Methicillin Resistant *Staphylococcus aureus*)
    - VRE (Vancomycin Resistant *Enterococcus*)

  Additionally, to better simulate the complex microbial environment of the oral cavity, additional antimicrobial contact tests using the ASTM E2180-24 methodology were performed on human saliva samples spiked with a mixed consortium of clinically relevant microorganisms to reflect a more realistic clinical challenge scenario:
    - *Candida albicans*
    - *Candida glabrata*
    - *Candida tropicalis*
    - *Streptococcus mutans*
    - *Streptococcus mitis*
    - Methicillin-resistant *Staphylococcus aureus* (MRSA)
    - Vancomycin-resistant *Enterococcus* (VRE).

  The *in vitro* antimicrobial contact test results showed that the subject device, Glidewell™ Denture Base Resin, reduced the viable count of each of the individual tested

microorganisms by more than 99.9% in the single species contact test, as compared to the control samples of regular denture without antimicrobial agent after 24 hours of contact. The test results on the human saliva samples spiked with key microorganisms showed a reduction rate of more than 99.99% of the total aerobic bacteria, total fungi, and total Streptococci species, as well as a reduction rate of more than 99.7% of each of the spiked key microorganisms, as compared to the control samples of regular denture without antimicrobial agent after 24 hours of contact, indicating a strong bactericidal and fungicidal effect under the *in vitro* test conditions.

- Long-term antimicrobial efficacy testing was conducted in accordance with ASTM E2180-24 and ASTM F1980-16, to evaluate the durability of the antimicrobial agent over time. These tests included both real-time aging for 6 months and accelerated aging conditions that simulate real-time aging at intervals of 1 year, 1.5 years, 2 years, 2.5 years, and 3 years. Antimicrobial effectiveness was evaluated against selected microorganisms known to be primary contributors to denture stomatitis, including:
    - *Streptococcus mutans*
    - *Candida albicans*

  Both the long-term antimicrobial test results under accelerated aging condition equivalent to 3 years of 'real use' and the real-time antimicrobial test results up to 6 months show a reduction of the viable counts of the tested microorganisms (*S. mutans* and *C. albicans*) maintained >99.99% level as compared to the control samples of regular denture without antimicrobial agent.

Visual Shade Match, Printing Validation and Printing Accuracy

Visual shade match was performed to verify that the color accuracy and consistency requirements for the subject device, Glidewell™ Denture Base Resin, were met for all the three different shades.

Meanwhile, printing accuracy test, as well as additional physical property tests and shade evaluation were performed to validate that the physical output of the additive manufacturing system used for the subject device, including all the compatible printers (Asiga Max, Asiga PRO 4K), post-curing units (Form Cure, iLuxCure Pro) and software (Asiga Composer), meet the design input dimensions within the pre-specified tolerance and does not impact the physical properties and shades. The samples were printed at 0°, 45° and 90° angle to validate that the finished appliances 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, Glidewell™ Denture Base Resin, can be reliably fabricated with consistent output quality at different print directions within the build space and at different build plate locations using the compatible additive manufacturing system and procedure.

Material Reuse Test

Material reuse test was performed following the material reuse instructions in the IFU after it has been exposed to repeated printing cycles until minimal volume of resin is left to successfully print the test samples. The samples printed from the resin after this repeated reuse were tested on flexural strength, flexural modulus, maximum stress intensity factor, total fracture work and printing accuracy. The test results met the standard passing criteria for all the tests, which indicated that

the resin was not significantly degraded during printing after repeated reuse under the worst-case scenario.

Biocompatibility

Biological evaluation within a risk management process was performed in accordance with ISO 10993-1:2018 and ISO 14971:2019. Based on the evaluation, biocompatibility tests were conducted for the applicable endpoints, and the testing results show that there is no biocompatibility concern for the subject device, Glidewell™ Denture Base Resin, regarding cytotoxicity, skin sensitization, oral mucosal irritation, acute systemic toxicity, and genotoxicity. The results of the testing were used to address questions related to substantial equivalence based on differences in chemical composition between the subject device, Glidewell™ Denture Base Resin, and the predicate device, Glidewell™ 3DP Denture Base Resin (K213765).