September 12, 2024

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

Re: K241493
Trade/Device Name: Glidewell™ 3DP 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: August 14, 2024
Received: August 14, 2024

Dear Li Jiahe:

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
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

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)*

K241493

Device Name

Glidewell™ 3DP Denture Base Resin

Indications for Use *(Describe)*

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.

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.

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K241493

510(k) Summary

Date Prepared: August 12, 2024

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 (Hannah) 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: Glidewell™ 3DP 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

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

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-cured methacrylic material with photo initiators that form a polymer during 3D printing. Glidewell™ 3DP 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 provided by the DLP printer (405nm wavelength), and the post-curing light box polymerize the resin which forms a hardened denture base. Once cured, Glidewell™ 3DP Denture Base Resin has the mechanical property that meets the performance criteria for Type 4: Light-activated materials as defined in the FDA-recognized consensus standard ISO 20795-1:2013 Dentistry - Base polymers – Part 1: Denture base polymers, including flexural strength, flexural modulus, water sorption and water solubility.

The subject device, Glidewell™ 3DP Denture Base Resin, has the same formulation and manufacturing process as the predicate device, Glidewell™ 3DP Denture Base Resin (K213765), which contains silver sodium hydrogen zirconium phosphate. *In vitro* studies on the subject device, Glidewell™ 3DP 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™ 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.

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

The subject device, Glidewell™ 3DP 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™ 3DP Denture Base Resin, has the same design as the as the predicate device, Glidewell™ 3DP Denture Base Resin (K213765). The material composition and

principle of operation are the same, thus the same technological characteristics regarding physical performance.

The formulation of the Glidewell™ 3DP Denture Base Resin contains silver sodium hydrogen zirconium phosphate as the antimicrobial agent. The silver containing filler is known to exhibit antimicrobial action against bacteria and fungi. This submission includes additional *in vitro* testing data on the antimicrobial action of the Glidewell™ 3DP Denture Base Resin regarding the common bacteria and fungi strains tested. Clinical studies have not been conducted to demonstrate that the presence of silver sodium hydrogen zirconium phosphate in Glidewell™ 3DP Denture Base Resin results in improved clinical outcomes.

Attributes		Subject Device	Predicate Device	Comparison
Device Name		Glidewell™ 3DP Denture Base Resin	Glidewell™ 3DP Denture Base Resin	N/A
510(k)		TBD	(K213765)	N/A
Regulation		21 CFR 872. 3760	21 CFR 872. 3760	Same
Product Code		EBI	EBI	Same
Classification		Class II	Class II	Same
Manufacturer		Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Intended Use/ Indications for Use		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
Prescription Device		Yes	Yes	Same
Design Characteristic	Material Composition	Methacrylate/dimethacrylate-based resin with photo-initiator, stabilizer, fillers and pigments.	Methacrylate/dimethacrylate-based resin with photo-initiator, stabilizer, fillers and pigments.	Same
	Additive Manufacturing	DLP printers utilizing wavelengths of 405nm.	DLP printers utilizing wavelengths of 405nm.	Same. Additional Asiga printer model within the compatible printer type has been validated for the subject 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	Light-cured denture base resin 3D printed using digital light processing (DLP) technology, which involves the light-mediated conversion of a liquid resin containing	Same

Attributes		Subject Device	Predicate Device	Comparison
		monomer and oligomer photopolymers to a solid object with the desired physical properties for removable dentures and baseplates.	monomer and oligomer photopolymers to a solid object with the desired physical properties for removable dentures and baseplates.	
	Performance Testing	Meets the performance standards for Type 4 denture base polymer per ISO 20795-1:2013. *In vitro* antimicrobial testing conducted per ASTM E2180-07 and ASTM E2647-13 (modified method) on • 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)	Meets the performance standards for Type 4 denture base polymer per ISO 20795-1:2013.	Same physical performance. The subject device included additional in vitro testing data on the antimicrobial action of the Glidewell™ 3DP Denture Base Resin regarding the common bacteria and fungi strains tested.
	Sterility	Non-sterile	Non-sterile	Same
	Biocompatibility	Biocompatible per testing results for all applicable end points per ISO 10993-1:2018 and ISO 7405:2018.	Biocompatible per testing results for all applicable end points per ISO 10993-1:2018 and ISO 7405:2018.	Same

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

In vitro studies were conducted to evaluate the activity of the incorporated antimicrobial agent, silver sodium hydrogen zirconium phosphate, in the subject device, Glidewell™ 3DP Denture Base Resin. The antimicrobial tests conducted were to assess the effectiveness of the subject device on reduction of selected microorganisms on surface contact and reduction of biofilm formation and build up. The tests conducted include the following:

- Antimicrobial contact tests per ASTM E2180-07 *Standard test method for determining the activity of incorporated antimicrobial agent(s) in polymeric or hydrophobic materials, 2017* were conducted on the following selected microorganisms:

    - 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)

The *in vitro* antimicrobial contact test results show that the subject device, Glidewell™ 3DP Denture Base Resin, reduced the viable count of all the tested microorganisms by more than 99.9% 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 effect tests under accelerated aging conditions to simulate real-time aging for 1 year, 1.5 years, 2 years, 2.5 years, and 3 years were conducted per ASTM E2180-07 *Standard Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) in Polymeric or Hydrophobic Materials* and ASTM F1980-16 *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*, as well as real-time aging test over 6 months. The tests were conducted on the following selected microorganisms, which are the main microorganisms that cause denture stomatitis:
    - Streptococcus mutans
    - Candida albicans

  The long-term antimicrobial test results under accelerated aging condition equivalent to 3 years of 'real-use' show the reduction of the viable counts of the tested microorganisms (S. mutans and C. albicans) maintained the >99.9% level as compared to the control samples of regular denture without antimicrobial agent. In addition, the real-time antimicrobial test results up to 6 months show the reduction of the viable counts of the tested microorganisms (S. mutans and C. albicans) remained at significantly higher levels as compared to the control samples over the tested period. The test results support the long-term *in vitro* antimicrobial effectiveness of the subject device, Glidewell™ 3DP Denture Base Resin.

- Long-term Antibiofilm test was performed per the modified ASTM E2647-13 *Standard Test Method for Quantification of Pseudomonas aeruginosa Biofilm Grown Using Drip Flow Biofilm Reactor with Low Shear and Continuous Flow* developed by Center for Biofilm Engineering, Montana State University. The ASTM E2647-13 testing method was

modified to better simulate the 'real-use' conditions of the denture in the patient's mouth. The test was conducted on the following selected microorganisms, which are the main organisms that cause denture stomatitis:

- Streptococcus mutans
- Candida albicans

The long-term antibiofilm test results show that the subject device, Glidewell™ 3DP Denture Base Resin, prevented the biofilm formation and growth of the tested microorganisms (S. mutans and C. albicans) with a reduction rate of over 90% for S. mutans and over 70% for C. albicans. The results provide further support for the long-term *in vitro* antimicrobial effectiveness the subject device, Glidewell™ 3DP Denture Base Resin..

Clinical studies have not been conducted to demonstrate that the presence of silver sodium hydrogen zirconium phosphate in Glidewell™ 3DP Denture Base Resin results in improved clinical outcomes.

The subject device, Glidewell™ 3DP Denture Base Resin, has identical design, including chemical composition and manufacturing process, as the predicate device, Glidewell™ 3DP Denture Base Resin (K213765). Therefore, the subject device has the same physical properties as the predicate device, and physical testing data submitted with the predicate device (K213765), including flexural strength, flexural modulus, water sorption and water solubility per ISO 20795-1: 2013 *Dentistry – Base polymers Part 1: Denture base polymers*, apply to the subject device. No additional physical property test is needed.

In addition, printer validation, including printing accuracy and printing orientation validation, has been performed to add an additional compatible printer model, Asiga PRO 4K, to the list of compatible printers on the device labeling.