June 22, 2022

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

Re: K213765
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: March 22, 2022
Received: March 24, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Michael E. Adjodha, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213765

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PRISMATIK DENTALCRAFT, INC.

K213765
510(k) Summary

I. SUBMITTER

Prismatik Dentalcraft, Inc.
2144 Michelson Drive,
Irvine, CA 92612, USA

Primary Contact Person: Jiahe Li, Regulatory Affairs Specialist
Email: Jiahe.Li@glidewelldental.com
Phone: (949) 222-3516

Secondary Contact Person: Herbert Crane, VP RA/QA
Email: Herbert.Crane@glidewelldental.com
Phone: (949) 222-3531

Date Prepared: November 30, 2021

II. DEVICE

Name of Device: Glidewell™ 3DP Denture Base Resin
Common Name or Usual Name: Denture Base Resin
Classification Name: Denture relining, repairing, or rebasing resin (21 CFR 872.3760)
Regulatory Class: Class II
Product Code: EBI

III. PRIMARY PREDICATE DEVICE

GR-14 Resin System (K210298)

IV. DEVICE DESCRIPTION

Glidewell™ 3DP Denture Base Resin is a light-cured resin for the fabrication of removable 3DP denture bases, including full and partial dentures, fabricated in a professional dental setting. The resin is compatible with DLP printers utilizing wavelengths of 405nm and is offered in G1 (standard pink), G3 (medium pink) and G4 (dark pink) shades formulated to match gingival tissue.

V. 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.

PRISMATIK DENTALCRAFT, INC.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics	**Subject Device** Glidewell™ 3DP Denture Base Resin	**Predicate Device** GR-14 Resin System (K210298)	**Comparison**
Manufacturer	Prismatik Dentalcraft, Inc.	Pro3dure Medical GmbH	N/A
Product Code	EBI	EBI	Same
Prescription Device	Yes	Yes	Same
Intended Use	Denture base resin for partial and full denture	Denture base resin for partial and full denture	Same
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.	The GR-14.1 denture is a light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment. The GR-14.1 denture is indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates. The GR-14.2 denture HI is a light-curable polymerizable resin intended to be used in conjunction with extraoral curing light equipment. The GR-14.2 denture HI is indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates.	Only the trade names are different between the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298). The second part of the Indications for Use statement for the predicate device, GR-14 Resin System (K210298) is the same as the first part, except for the change in the trade name from GR-14.1 to GR-14.2 denture HI. The repeated part is not included in the case of the subject device, Glidewell™ 3DP Denture Base Resin., as it would be redundant.

Technological Characteristics		**Subject Device** Glidewell™ 3DP Denture Base Resin	**Predicate Device** GR-14 Resin System (K210298)	**Comparison**
Design Characteristics	General Design	Light-cured denture base resin using 3D printing technology to convert the liquid resin to solid dentures and baseplates	Light-cured denture base resin using 3D printing technology to convert the liquid resin to solid dentures and baseplates	Same
	Material composition	Methacrylate/dimethacrylate-based resins with photo-initiator, stabilizer, filler and pigments.	Methacrylate /dimethacrylates, photo-initiator, stabilizer, filler and pigments.	Substantially equivalent
	Additive Manufacturing System	Glidewell™ 3DP Denture Base Resin is intended to be used in conjunction with an additive Computer- Aided Manufacturing (CAM) and curing system such as Nyomo, Rapidshape, Envisiontec or Asiga Systems.	The GR-14 Resin System is intended to be used in conjunction with an additive Computer- Aided Manufacturing (CAM) and curing system such as Nyomo, Rapidshape, Envisiontec or Asiga Systems.	Same
	Bench Testing (physical property)	Meets the performance standards for Type 4 denture base polymer per ISO 20795-1	Meets the performance standards for Type 4 denture base polymer per ISO 20795-1	Same
	Biocompatibility	Biocompatible per testing results for all applicable end points per ISO 10993 and ISO 7405	Biocompatible per testing results for all applicable end points per ISO 10993 and ISO 7405	Same
	Sterility	Non-Sterile	Non-Sterile	Same

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, Glidewell™ 3DP Denture Base Resin, is substantially equivalent to the primary predicate device, GR-14 Resin System (K210298) in intended use/indications for use and technological characteristics, including technical specifications/features, material and principles of operation.

The subject device, Glidewell™ 3DP Denture, has the same intended use as the predicate device, GR-14 Resin System (K210298) as denture base resin. The subject device, Glidewell™ 3DP Denture, has the same Indications for Use Statement (IFUS)

as the predicate device, GR-14 Resin System (K210298), except for the device trade name. Both the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298) are light-curable polymerizable resin indicated for the fabrication and repair of full and partial removable dentures and baseplates. Both the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298) are additively manufactured and cured using extraoral curing light equipment. Both the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298) are indicated for prescription use only.

The subject device, Glidewell™ 3DP Denture Base Resin, is substantially equivalent to the predicate device, GR-14 Resin System (K210298) in technical features. The subject device, Glidewell™ 3DP Denture Base Resin, was tested according to the test methods defined in the FDA-recognized consensus standard *ISO 20795-1 Dentistry - Base polymers – Part 1: Denture base polymers* for key physical properties, including flexural strength, flexural modulus, water sorption and water solubility. The testing results showed that the subject device, Glidewell™ 3DP Denture Base Resin met the same performance criterial for Type 4: Light-activated materials set forth in *ISO 20795-1* as the predicate device, GR-14 Resin System (K210298).

The subject device, Glidewell™ 3DP Denture Base Resin and the predicate device, GR-14 Resin System (K210298) are similar in material composition. Both the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298) are methacrylate-based resins with photo-initiator, stabilizer, filler and pigments. Despite the actual difference that might exist between the formulations, the difference does not affect the safety and effectiveness for the indended use, as verified by the safety and performance testing.

The subject device, Glidewell™ 3DP Denture Base Resin, is substantially equivalent to the predicate device, GR-14 Resin System (K210298) in terms of principle of operation. Both the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298) are 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 solid object with the desired physical properties for removable dentures and baseplates.

VII. PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence include:

- Flexural strength and flexural modulus, according to ISO 20795-1: 2013
- Water sorption and water solubility, according to ISO 20795-1: 2013
- Visual shade match and L*a*b shade verification
- Printing accuracy and printing orientation validation
- Packaging validation

- Biocompatibility

No clinical data is included in this submission.

Flexural Strength and Flexural Modulus

The subject device, Glidewell™ 3DP Denture Base Resin, was tested for flexural strength and flexural modulus in accordance to ISO 20795-1: 2013. The flexural strength for Glidewell™ 3DP Denture Base Resin was tested to be greater than 65 MPa and the flexural modulus was tested to be greater than 2000 MPa, meeting ISO 20795-1: 2013 requirement for Type 4: Light-activated materials. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298).

Water Sorption and Water Solubility

The subject device, Glidewell™ 3DP Denture Base Resin, was tested for water sorption and water solubility in accordance to ISO 20795-1: 2013. The water sorption for Glidewell™ 3DP Denture Base Resin was tested to be less than 32 µg/mm3 and the water solubility was tested to be less than 1.6 µg/mm3, meeting ISO 20795-1: 2013 requirement for Type 4: Light-activated materials. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298).

Visual Shade Match and L*a*b Shade Verification

Visual shade match and L*a*b shade verification were performed on samples of the G1, G3 and G4 shade within a batch and between batches. The results met the acceptance criteria and conformed that the subject device, Glidewell™ 3DP Denture Base Resin, met the color accuracy and consistency requirements for all its different shades. The results of the testing were used to address questions related to substantial equivalence based on differences in device design between the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298).

Printing Accuracy and Printing Orientation Validation

Printing accuracy test was performed to validate that the physical output of the additive manufacturing system and procedure for Glidewell™ 3DP Denture Base Resin is able to meet design input dimensions within the pre-specified tolerance. Printing orientation test was performed to validate that the subject device, Glidewell™ 3DP Denture Base Resin, printed at different print direction within the build space relative to the device orientation and at different build plate locations are able to meet the same performance criteria. The results met the pre-specified acceptance criteria and demonstrated that the subject device, Glidewell™ 3DP Denture Base 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 results of the testing were used to address questions related to substantial

equivalence based on differences in additive manufacturing process between the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298).

Packaging Validation

Packaging validation was also performed for the subject device, Glidewell™ 3DP Denture Base Resin. Per ASTM D4169-14, the shipping unit was tested for manual handling, compressive loads, repetitive shocks from vibration, vertical vibration environments, concentrated impacts and secondary manual handling drops. After the tests, the shipping containers were visually inspected for any damages. It was determined that Glidewell™ 3DP Denture Base Resin with its respective packaging, is suitable for use. The results of the testing were used to address questions related to substantial equivalence based on differences in product packaging between the subject device, Glidewell™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298).

Biocompatibility

Biological evaluation within a risk management process was performed in accordance with ISO 10993-1:2018 and ISO 14971:2019. Based on the biocompatibility testing results, it was determined that there is no biocompatibility concern for the subject device, Glidewell™ 3DP Denture Base Resin, for its intended use with regard to cytotoxicity, skin sensitization, oral mucosal irritation, genotoxicity, subchronic toxicity, subacute systemic toxicity or systemic (acute) toxicity. 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™ 3DP Denture Base Resin, and the predicate device, GR-14 Resin System (K210298).

VIII. CONCLUSION

Based on technological characteristics and non-clinical test data included in this submission, the subject device, Glidewell™ 3DP Denture Base Resin, has been shown to be substantially equivalent to the predicate device, GR-14 Resin System (K210298).