February 17, 2023

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

Re: K223798
Trade/Device Name: Glidewell TuffSplint™ Appliance Resin
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: December 15, 2022
Received: December 19, 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,

Bobak Shirmohammadi -S

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)*
K223798

Device Name
Glidewell TuffSplint™ Appliance Resin

Indications for Use *(Describe)*
Glidewell TuffSplint™ Appliance Resin is indicated for the fabrication of orthodontic and dental appliances such as bite planes, mouthguards, nightguards, splints and repositioners.

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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PRISMATIK DENTALCRAFT, INC.

K223798

510(k) Summary

I. SUBMITTER

Prismatik Dentalcraft, Inc.
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Phone: (949) 838-1321
Date Prepared: December 15, 2022

II. DEVICE

Name of Device: Glidewell TuffSplint™ Appliance Resin
Classification Product Code: MQC
Regulatory Class: Unclassified
Common Name: Mouthguard, Prescription;
Classification Name: N/A, Pre-Amendment
Subsequent Product Code: KMY
Regulatory Class: Class I
Common Name: Positioner, Tooth, Preformed
Classification Name: Preformed tooth positioner

III. PRIMARY PREDICATE

KeyPrint KeySplint Soft Resin (K183598)

IV. DEVICE DESCRIPTION

Glidewell TuffSplint™ Appliance Resin is a light-cured resin for the fabrication of orthodontic and dental appliances. The resin can be used in DLP printers utilizing a wavelength of 385nm. The final medical device is a custom fitted appliance that is compliant to the dental professional's diagnosis and prescription. Glidewell TuffSplint™ Appliance Resin, in its final fabricated form, is a removable appliance that is fitted to a patient's oral anatomy and is maintained by the patient. The mechanism of a patient fitting starts with creating an impression of the patient's teeth via traditional or digital techniques, and then transferring that impression into a finished appliance via a validated 3D printing workflow.

V. INDICATIONS FOR USE

Glidewell TuffSplint™ Appliance Resin is indicated for the fabrication of orthodontic and dental appliances such as bite planes, mouthguards, nightguards, splints and repositioners.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics		**Subject Device** Glidewell TuffSplint™ Appliance Resin	**Predicate Device** KeyPrint KeySplint Soft Resin (K183598)	**Comparison**
Manufacturer		Prismatik Dentalcraft, Inc.	Keystone Industries	N/A
Product Code		MQC, KMY	MQC, KMY	Same
Prescription Device		Yes	Yes	Same
Intended Use		Resin for orthodontic and dental appliances	Resin for orthodontic and dental appliances	Same
Indications for Use		Glidewell TuffSplint™ Appliance Resin is indicated for the fabrication of orthodontic and dental appliances such as bite planes, mouthguards, nightguards, splints and repositioners.	The KeyPrint KeySplint Soft device is indicated for the fabrication of orthodontic and dental appliances such as bite planes, mouthguards, nightguards, splints and repositioners.	The indications for use are the same except for the device trade name.
Design Characteristics	General Design	Light-cured resin using 3D printing technology to convert the liquid resin to solid orthodontic and dental appliances.	Light-cured resin using 3D printing technology to convert the liquid resin to solid orthodontic and dental appliances.	Same
	Material composition	Light cured methacrylate based-resin.	Light cured methacrylate based-resin.	Substantially equivalent
	Additive Manufacturing System	Glidewell TuffSplint™ Appliance Resin is intended to be used in conjunction with an additive Computer- Aided Manufacturing (CAM) and curing system.	The KeyPrint KeySplint Soft device is intended to be used in conjunction with an additive Computer- Aided Manufacturing (CAM) and curing system.	Same

Technological Characteristics		**Subject Device** Glidewell TuffSplint™ Appliance Resin	**Predicate Device** KeyPrint KeySplint Soft Resin (K183598)	**Comparison**
	Bench Testing (physical property)	Physical properties according to • ISO 20795-2: Flexural Strength, Flexural Modulus, Water Sorption/Solubility • ASTM D638: Tensile Strength, Tensile Modulus, Elongation	Physical properties according to • ASTM D790: Flexural Properties • ISO 20795-2: Flexural Strength, Flexural Modulus, Water Sorption/Solubility • ASTM D638: Tensile Strength, Tensile Modulus, Elongation	The predicate device was tested for flexural properties according to ASTM D790 in addition to ISO 20795-2. The difference has no impact on the substantial equivalence determination.
	Biocompatibility	Biocompatible per testing results according to ISO 10993-1	Biocompatible per testing results according to ISO 10993-1	Same
	Sterility	Non-Sterile	Non-Sterile	Same

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, Glidewell TuffSplint™ Appliance Resin, is substantially equivalent to the primary predicate device, KeyPrint KeySplint Soft Resin (K183598) in intended use, indications for use and technological characteristics, including technical specifications/features, material and principles of operation.

The subject device, Glidewell TuffSplint™ Appliance Resin, has the same intended use as the predicate device, KeyPrint KeySplint Soft Resin (K183598) as material for fabricating prescription mouthguards and preformed tooth positioners. The subject device, Glidewell TuffSplint™ Appliance Resin, has the same Indications for Use Statement (IFUS) as the predicate device, KeyPrint KeySplint Soft Resin (K183598), except for the device trade name. Both the subject device, Glidewell TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598) are dental resin indicated for the fabrication of orthodontic and dental appliances such as bite planes, mouthguards, nightguards, splints and repositioners.

The subject device, Glidewell TuffSplint™ Appliance Resin, is substantially equivalent to the predicate device, KeyPrint KeySplint Soft Resin (K183598) in technical specifications/features. The product specifications of the subject device, Glidewell TuffSplint™ Appliance Resin, is based on benchmarking comparable

devices with similar indications for use on the market, including the predicate device, KeyPrint KeySplint Soft Resin (K183598). The same property testing according to ISO 20795-2:2013 and ASTM D638-14 that applied to the predicate device, KeyPrint KeySplint Soft Resin (K183598), were performed on the subject device, Glidewell TuffSplint™ Appliance Resin, including flexural strength, flexural modulus, water sorption, water solubility, tensile strength, tensile modulus and elongation. The physical property of the subject device, Glidewell TuffSplint™ Appliance Resin, passed the threshold of performance criteria in ISO 20795-2:2013 when applicable to the design, and met the same performance criteria used by the predicate device, KeyPrint KeySplint Soft Resin (K183598).

The subject device, Glidewell TuffSplint™ Appliance Resin and the predicate device, KeyPrint KeySplint Soft Resin (K183598) are similar in material composition. Both the subject device, Glidewell TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598) are light cured methacrylate-based resin. 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 TuffSplint™ Appliance Resin, is substantially equivalent to the predicate device, KeyPrint KeySplint Soft Resin (K183598) in terms of principle of operation. Both the subject device, Glidewell TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598) are light-cured resin in liquid form that through light-mediated conversion can be fabricated into a solid finished device. The finished device has the desired physical properties suitable for orthodontic and dental appliances such as bite planes, mouthguards, nightguards, splints and repositioners.

VII. PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence include:

- Flexural strength and flexural modulus, according to ISO 20795-2:2013
- Water sorption and water solubility, according to ISO 20795-2:2013
- Tensile Strength, Tensile Modulus and Elongation, according to ASTM D638-14
- Packaging validation
- Biocompatibility

No clinical data is included in this submission.

Flexural Strength and Flexural Modulus

The subject device, Glidewell TuffSplint™ Appliance Resin, was tested for flexural strength and flexural modulus in accordance to the test methods outlined in ISO 20795-2:2013. All the testing results met the acceptance criteria. 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 TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598).

Water Sorption and Water Solubility

The subject device, Glidewell TuffSplint™ Appliance Resin, was tested for water sorption and water solubility in accordance to ISO 20795-2:2013. All the testing results met the acceptance criteria. 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 TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598).

Tensile Strength, Tensile Modulus and Elongation

The subject device, Glidewell TuffSplint™ Appliance Resin, was tested for tensile strength, tensile modulus and elongation in accordance to ASTM D638-14. All the testing results met the acceptance criteria. 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 TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598).

Printing Accuracy and Printing Orientation Validation

A printing accuracy test was performed to validate that the physical output of the additive manufacturing system and procedure for Glidewell TuffSplint™ Appliance Resin is able to meet design input dimensions within the pre-specified tolerance. A printing orientation test was performed 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 can meet the same performance criteria. The results met the pre-specified acceptance criteria and demonstrated that the subject device, Glidewell TuffSplint™ Appliance 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.

Packaging Validation

Packaging validation tests were performed for the subject device, Glidewell TuffSplint™ Appliance Resin. Per ASTM D4169-16, the shipping unit was tested for manual handling, compressive loads, repetitive shocks from vibration, low pressure hazard environment, vehicle & air transport vibration, concentrated impacts and secondary manual handling drops. In addition, the integrity of the packaging was tested on heated environment (55°C) under the ullage test. It was determined that Glidewell TuffSplint™ Appliance Resin with the 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 TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598).

Biocompatibility

The subject device, Glidewell TuffSplint™ Appliance Resin, was tested in accordance with ISO 10993-1:2018. Based on the biocompatibility testing results, it was determined that there is no biocompatibility concern for the subject device. 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 TuffSplint™ Appliance Resin, and the predicate device, KeyPrint KeySplint Soft Resin (K183598).

VIII. CONCLUSION

Based on technological characteristics and non-clinical test data included in this submission, the subject device, Glidewell TuffSplint™ Appliance Resin, has been shown to be substantially equivalent to the predicate device, KeyPrint KeySplint Soft Resin (K183598).