August 8, 2024

Pro3dure Medical
% Patricia Kontoudis
Regulatory Affairs Specialist
Kontoudis Regulatory Consulting, LLC
804 Umbra St.
Baltimore, Maryland 21224

Re: K231775
Trade/Device Name: GR Resin System MSI
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: June 10, 2024
Received: June 11, 2024

Dear Patricia Kontoudis:

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.

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.

510(k) Number *(if known)*
K231775

Device Name
GR Resin System MSI

Indications for Use *(Describe)*

The printodent® GR-10 guide | MSI is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of orthodontic and dental objects such as splints.

The printodent® GR-19.1 OA is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental objects such as mouthguards, nightguards, splints, repositioners and retainers.

The printodent® GR-19.1 OA | MSI is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental objects such as mouthguards, nightguards, splints, repositioners and retainers.

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.

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6. 510(k) Summary

Device Trade Name:	GR Resin System MSI
Manufacturer:	Pro3dure Medical GmbH Am Burgberg 13 58642 Iserlohn Germany
Contact:	Mr. Frank Gischer Phone: +49 (0)2374 920050-14 Fax: +49 (0)2374 920050-50 Frank.gischer@pro3dure.com
Prepared by:	Ms. Patricia Kontoudis Regulatory Affairs Specialist Kontoudis Regulatory Consulting, LLC 804 Umbra Street Baltimore, MD 21224 Phone: (443)722-0126 Email: tricia@kontoudisconsulting.com
Date Prepared:	June 10, 2024
Classification:	Unclassified
Product Codes:	MQC
Additional Product Codes:	KMY
Primary Predicate Device:	GR Splint Resin System (K211415)
Additional Predicates:	KeyPrint KeySplint hard (K203000) KeyPrint KeySplint Soft (K183598)
Reference Device:	Pro3dure GR-17 Resin System (K201827)
Indications for Use:	The printodent® GR-10 guide | MSI is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of orthodontic and dental objects such as splints. The printodent® GR-19.1 OA is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental objects such as mouthguards, nightguards, splints, repositioners and retainers.

	The printodent® GR-19.1 OA | MSI is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental objects such as mouthguards, nightguards, splints, repositioners and retainers.
Device Description:	GR-10 guide MSI is made of functional methacrylic resins and inorganic fillers and the GR-19.1 OA, and GR-19.1 OA MSI consist of functional (meth)acrylic resins, initiators, dyes, stabilisers and lactam. The GR-10 guide MSI, and GR-19.1 OA MSI are available in ocean blue shade, and the GR-19.1 OA is available in clear transparent. The resin is a liquid photo-curable material that is polymerized by image projection systems at ≤ 405 nm to create dental appliances. The GR Resin System MSI 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
Performance Testing:	Performance testing for the GR Resin System MSI was performed in accordance with ISO 20795-2 including Flexural Strength, and Flexural modulus / Bending module, Water Sorption and Solubility.
Biocompatibility:	Biocompatibility testing was conducted in accordance with ISO 10993-1.
Shelf-Life:	The shelf life of the GR Resin System MSI is 2 years. Testing was performed in accordance with ASTM F1980-16.

Comparison to Predicate Devices:

Device	Subject Device:	Primary Predicate Device: GR Splint Resin System (K211415)	Additional Predicate Device: KeyPrint KeySplint Hard (K203000)	Additional Predicate Device: KeyPrint KeySplint Soft (K183598)
Manufacturer	**Pro3dure Medical GmbH**	**Pro3dure Medical GmbH**	**Mycone Dental Supply Co. Inc.**	**Mycone Dental Supply Co. Inc.**
Indications for use	The printodent® GR-10 guide | MSI is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of orthodontic and dental objects such as splints. The printodent® GR-19.1 OA is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental objects such as mouthguards, nightguards, splints, repositioners and retainers. The printodent® GR-19.1 OA | MSI is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment for the fabrication, by additive manufacturing, of dental objects such as mouthguards, nightguards, splints, repositioners and retainers	The GR Splint Resin System is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment: The GR-10 guide is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as splints. The GR-19 OA is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as nightguards, splints, repositioners and retainers. The GR-22 flex is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, and repositioners.	KeyPrint® KeySplint Hard™ is a biocompatible photopolymer resin intended for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners, and retainers	The KeyPrint® KeySplint Soft™ device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.
	Comparison: The subject and the predicate devices have the same indications.			

Chemical Description	Methacrylate Monomers, photo initiator	Contains acrylate monomers and oligomers, photo initiator	Contains acrylate monomers and oligomers, photo initiator	Contains acrylate monomers and oligomers, photo initiator
	Comparison: The subject and the predicate devices have similar chemical characterization.			
Manufacturing Technology	Additive	Additive	Additive	Additive
	Comparison: The subject and the predicate devices use additive manufacturing to fabricate the final product.			
Product State	Liquid	Liquid	Liquid	Liquid
	Comparison: The subject and the predicate devices are provided in liquid form.			
Curing Method	UV Light	UV Light	UV Light	UV Light
	Comparison: The subject and the predicate devices use the same curing method.			
Performance Testing	ISO 20795-2	ISO 20795-2	ISO 20795-2	ISO 20795-2
	Comparison: The subject and the predicate devices comply with the same performance standards.			
Biocompatibility	ISO 10993	ISO 10993	ISO 10993	ISO 10993
	Comparison: The subject and the predicate devices comply with the same biocompatible standards.			

Conclusion: The GR Resin System MSI is substantially equivalent in indications, technical characteristics, function, material, performance, biocompatibility, and shelf life to the predicate devices.