October 21, 2021

Pro3dure Medical GmbH
Patricia Kontoudis
Senior Specialist, Regulatory Affairs
Regulatory and Quality Solutions, LLC
2790 Mosside Blvd.
Monroeville, Pennsylvania 15146

Re: K211415
Trade/Device Name: GR Splint Resin System
Regulatory Class: Unclassified
Product Code: MQC, EBI, KMY
Dated: August 9, 2021
Received: August 25, 2021

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 (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,

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)*
K211415

Device Name
GR Splint Resin System

Indications for Use *(Describe)*
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 mouthguards, 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.

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."

5. 510(k) Summary K211415

Device Trade Name: GR Splint Resin System

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
Senior Specialist, Regulatory Affairs
Regulatory and Quality Solutions, LLC
2790 Mosside Blvd., Suite 800
Monroeville, PA 15146
Phone: (443)722-0126
pkontoudis@rqmplus.com

Date Prepared: April 30, 2021

Classification: Unclassified

Product Codes: MQC

Additional Product Codes: EBI, KMY

Primary Predicate Device: KeyPrint KeySplint Hard (K203000)

Additional Predicate: KeyPrint KeySplint Soft (K183598)

Reference Device: Pro3dure GR-17 Resin System (K201827)

Indications for Use: 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

mouthguards, 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.

Device Description: GR Splint Resin System includes the GR-10 Guide Resin, GR-19 OA Resin, and GR-22 flex Resin. The GR Splint Resin System is made of functional methacrylic resins and inorganic fillers.

The GR-10 Guide Resin, GR-19 OA Resin, GR-22 flex Resin It is available in light blue-transparent, clear transparent and rose-transparent shades. The resin is a liquid photo-curable material that is polymerized by image projection systems at 385 nm and 405 nm to create dental appliances. The GR-10 Guide Resin, GR-19 OA Resin, GR-22 flex Resin are 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 Splint Resin System was performed in accordance with ISO 20795-2 including Flexural Strength, Flexural modulus / Bending module, Water Sorption and Solubility, Fracture toughness, Total Work of Fracture Testing, Tensile Strength, and Elongation at Break.

Biocompatibility: Biocompatibility testing was conducted in accordance with ISO 10993-1.

Shelf-Life: The shelf life of the GR Splint Resin System is 2 years. Testing was performed in accordance with ASTM F1980-16.

Comparison to Predicate Devices:

Device	Subject Device	Primary Predicate Device: KeyPrint KeySplint Hard (K203000)	Additional Predicate Device: KeyPrint KeySplint Soft (K183598)
Manufacturer	**Pro3dure Medical GmbH**	**Mycone Dental Supply Co. Inc.**	**Keystone Industries**
Indications for use	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 mouthguards, 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
Comparison: The subject and the predicate devices have similar chemical characterization.			
Manufacturing Technology	Additive	Additive	Additive
Comparison: The subject and the predicate devices use additive manufacturing to fabricate the final product.			
Product State	Liquid	Liquid	Liquid
Comparison: The subject and the predicate devices are provided in liquid form.			
Curing Method	UV Light	UV Light	UV Light
Comparison: The subject and the predicate devices use the same curing method.			
Performance Testing	ISO 20795-2 ASTM D256 ISO 37	ISO 20795-2 ASTM D256 ISO 37	ISO 20795-2 ASTM D256 ISO 37
Comparison: The subject and the predicate devices comply with the same performance standards.			
Biocompatibility	ISO 10993	ISO 10993	ISO 10993
Comparison: The subject and the predicate devices comply with the same biocompatible standards.			

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