November 5, 2020

Pro3dure Medical GmbH
% Patricia Kontoudis
Specialist, Regulatory Affairs
Regulatory and Quality Solutions, LLC
2790 Mosside Blvd., Suite 800
Monroeville, Pennsylvania 15146

Re: K201827
Trade/Device Name: GR-17 Resin System
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG, PZY
Dated: October 6, 2020
Received: October 7, 2020

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,

For Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201827

Device Name
GR-17 Resin System

Indications for Use *(Describe)*

The GR-17 Resin System is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment.

The GR-17 temporary is indicated for the fabrication, by additive manufacturing, of temporary anterior dental restorations.

The GR-17.1 temporary is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and for the fabrication, by additive manufacturing, of preformed denture teeth to be used in a denture.

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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510(k) Summary

Device Trade Name	GR-17 Resin System (GR-17 temporary and GR-17.1 temporary It)
Manufacturer	Pro3dure Medical GmbH Am Burgberg 13 58642 Iserlohn Germany
Contact	Dr. Martin Klare Phone: +49 (0)2374 920050-11 Fax: +49 (0)2374 920050-50 martin.klare@pro3dure.com
Prepared by	Ms. Patricia Kontoudis Specialist, Regulatory Affairs Regulatory and Quality Solutions, LLC 2790 Mosside Blvd., Suite 800 Monroeville, PA 15146 Phone: (443)722-0126 pkontoudis@rqteam.com
Date Prepared	November 5, 2020
Common Name	Crown and Bridge, Temporary, Resin
Classification Name	Temporary Crown and Bridge Resin
Regulation Number	21 CFR 872.3770
Regulatory Class	Class II
Product Codes	EBG
Subsequent Product Code	PZY
Primary Predicate Device	DeltaMed e-Dent Temporary Resin and Extra-Oral Curing System (K102776)
Reference Device	Dentis Resin for Temporary Crown & Bridge (K180657) Dentca, Dentca Denture Teeth (K172398)

Indications for Use

The GR-17 Resin System is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment.

The GR-17 temporary is indicated for the fabrication, by additive manufacturing, of temporary anterior dental restorations.

The GR-17.1 temporary is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and for the fabrication, by additive manufacturing, of preformed denture teeth to be used in a denture.

Device Description

GR-17 Resin System includes the GR-17 temporary and GR-17.1 temporary It and is made of functional methacrylic resins and inorganic fillers with particle sizes from 0.4 to 3 microns. It is available in seven shades based on the shade guide, A1, A2, A3, A3.5, B1, B2 and bleach. The resin is a liquid photo-curable material that is polymerized by image projection systems at 405nm to create temporary dental restorations, and preformed denture teeth to be used in a denture. The GR-17 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.

Performance Testing

Performance testing for the GR-17 Resin System was performed in accordance with ISO 10477 and ISO 22112.

Biocompatibility

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

Shelf Life

The shelf life of the GR-17 Resin System is 2 year. Testing was performed in accordance with ASTM F1980-16.

Comparison to Predicate

	GR-17 Resin System	**Predicate Device: e-Dent Temporary Resin and Extra-Oral Curing System**	**Reference Device: Resin for Temporary Crown & Bridge**	**Reference Device: Dentca Denture Teeth**
Manufacturer	**Pro3dure Medical GmbH**	**DeltaMed GmbH**	**Dentis Co. Ltd.**	**Dentca, Inc.**
510(k) Number	K201827	K102776	K180657	K172398

Indications for use	The GR-17 Resin System is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. The GR-17 temporary is indicated for the fabrication, by additive manufacturing, of temporary anterior dental restorations. The GR-17.1 temporary It is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and for the fabrication, by additive manufacturing, of preformed denture teeth to be used in a denture.	The e-DENT TEMPORARY resin is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment.	Resin for Temporary Crown & Bridge is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is less than 30 days in oral environment.	DENTCA Denture Teeth is a light-curable polymerizable resin to fabricate, by additive manufacturing, preformed denture teeth to be used in a denture.
Comparison: The GR-17 Resin System has similar indications as the predicate devices.				
Chemical Description	Methacrylate- based resin	Methacrylate- based resin	Methacrylate- based resin	Methacrylate- based resin
Comparison: The GR-17 Resin System has similar chemical characterization as the predicate devices.				
Acrylic Resin	Extra-oral light cure resin	Extra-oral light cure resin	Extra-oral light cure resin	Extra-oral light cure resin
Comparison: The GR-17 Resin System and the predicate devices are extra-oral light cure resins.				
Curing Method	UV Light	UV Light	UV Light	UV Light
Comparison: The GR-17 Resin System uses the same curing method as the predicate devices.				
Product State	Liquid	Liquid	Liquid	Liquid
Comparison: The GR-17 Resin System and the predicate devices are provided in liquid form.				
Physical and Mechanical Properties	Flexural Strength Modulus of Elasticity Water Absorption Solubility	Flexural Strength Modulus of Elasticity Water Absorption Solubility	Not Available	Modulus of Elasticity Water Absorption Solubility
Comparison: The GR-17 Resin System and the predicate devices are equivalent physical and mechanical properties.				
Manufacturing	Additive	Additive	Additive	Additive
Comparison: The GR-17 Resin System and the predicate devices use additive manufacturing to fabricate the final product.				
Standards	ISO 10477 ISO 22112 ISO 4049	ISO 10477 ISO 4049	ISO 10477	ISO 10477 ISO 22112
Comparison: The GR-17 Resin System and the predicate devices comply with the same standards.				
Biocompatibility	ISO 7405 ISO 10993	ISO 10993	ISO 10993	ISO 7405 ISO 10993
Comparison: The GR-17 Resin System and the predicate devices use biocompatible according to the same standards.				

Conclusion	The GR-17 Resin System is substantially equivalent in indications, technical characteristics, function, material, performance, biocompatibility, and shelf life to the predicate and reference devices.