May 5, 2021

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

Re: K210298
Trade/Device Name: GR-14 Resin System
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: March 4, 2021
Received: March 9, 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)*
k210298

Device Name
GR-14 Resin System

Indications for Use *(Describe)*
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.

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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5. 510(k) Summary - K210298

Device Trade Name: GR-14 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@rqteam.com

Date Prepared: March 4, 2021

Classification: 21 CFR 872.3760 - Denture relining, repairing, or rebasing resin

Class: II

Product Codes: EBI

Primary Predicate Device: NextDent Denture 3D+ (K191497)

Additional Predicate: Dentca Denture Base II (K162044)

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

Indications for Use:
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.

Device Description:
GR-14 Resin System includes the GR-14.1 denture and GR-14.2 denture HI and is made of functional methacrylic resins and inorganic fillers. It is available in three shades based on the shade guide, orange-pink, light-pink and deep-pink. The resin is a liquid photo-curable material that is polymerized by image projection systems at 405nm to create denture baseplates. 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. Preformed teeth are fixed into the denture base by extra gluing process with appropriate glue material.

Performance Testing:
Performance testing for the GR-14 Resin System was performed in accordance with ISO 20795-1 and ISO 22112, including Flexural Strength, Flexural modulus / Bending module, Bond Strength, Color Stability, Water Sorption and Solubility, Fracture toughness, and Total Work of Fracture Testing.

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

Shelf-Life:
The shelf life of the GR-14 Resin System is 2 year. Testing was performed in accordance with ASTM F1980-16.

Comparison to Predicate:

	Subject Device: GR-14. Resin System	**Predicate Device: NextDent Denture 3D+**	**Predicate Device: Dentca Denture Base II**
Manufacturer	**Pro3dure Medical GmbH**	**Vertex-Dental BV**	**DENTCA, Inc.**
510(k) Number	K210298	K191497	K162044
Indications for use	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	NextDent Denture 3D+ is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization. NextDent Denture 3D+ is intended exclusively for professional dental work. Fabrication of	DENTCA Denture Base II is a light-curable resin indicated for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat cured and auto polymerization. Fabrication of dental prosthetics with Dentca Denture Base II requires a computer-aided design and manufacturing (CAD/

	Subject Device: GR-14. Resin System	Predicate Device: NextDent Denture 3D+	Predicate Device: Dentca Denture Base II
Manufacturer	**Pro3dure Medical GmbH**	**Vertex-Dental BV**	**DENTCA, Inc.**
	indicated for the fabrication and repair, by additive manufacturing, of full and partial removable dentures and baseplates.	denture bases with NextDent Denture 3D+ requires a computer-aided and manufacturing (CAD/CAM) system that includes selected scanner, design software, additive printer and post-cure unit.	CAM) system that includes the following components: digital denture base files based on a digital impression, stereolithographic additive printer, and curing light equipment
Comparison: The GR-14 Resin System has the same indications as the predicate devices.			
Chemical Description	Multifunctional methacrylates/dimethacrylates, inhibitors, stabilizers, colors/pigments	Dimethacrylate-based resin with photo-initiator and pigments	Polymerizable monomers
Comparison: The GR-14 Resin System has similar chemical characterization as the predicate devices.			
Curing Method	UV Light	UV Light	UV Light
Comparison: The GR-14 Resin System uses the same curing method as the predicate devices.			
Product State	Liquid	Liquid	Liquid
Comparison: The GR-14 Resin System and the predicate devices are provided in liquid form.			
Manufacturing	Additive	Additive	Additive
Comparison: The GR-14 Resin System and the predicate devices use additive manufacturing to fabricate the final product.			
Performance Standards	ISO 20795-1 ISO 22112	ISO 20795-1	ISO 20795-1
Comparison: The GR-14 Resin System and the predicate devices comply with the same standards.			
Biocompatibility	ISO 7405 ISO 10993	ISO 10993	ISO 10993
Comparison: The GR-14 Resin System and the predicate devices use biocompatible according to the same standards.			

Conclusion:

The GR-14 Resin System is substantially equivalent in indications, technical characteristics, function, material. Performance, biocompatibility, and shelf life to the predicate devices.