DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 13,2016

Dental Direkt Gmbh
% Ms. Vera Buescher
Quality & Regulatory Manager
Dental DireK153490/S001kt Gmbh (former Dental Direkt Of Amerika Ug)
Industriezentrum 106-108
Spenge, 32139 DE

Re: K153490
Trade/Device Name: Dd Medical Polymers
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: April 11, 2016
Received: April 14, 2016

Dear Ms. Buescher:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K153490

Device Name: DD medical polymers:
- DD tempMED
- DD Bio Splint P

Indications for Use:

DD medical polymers are indicated for temporary (≤ 12 months) crowns, bridges and bite splints. Applications include both anterior and posterior structures.

Prescription Use ___**X**_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number: **K153490**

510(k) Summary

Submitter of 510(k)	Dental Direkt GmbH Industriezentrum 106-108 32139 Spenge / Germany
Contact Persons	Mr. Uwe Greitens, Authorized Representative Ms. Vera Büscher, Quality & Regulatory Manager Phone: +49 5225 86319-0 Fax: +49 5225 86319-99
Establishment Registration Number	3008347275
Date Prepared	2016/05/12
Trade Name of Device	DD medical polymers: - DD tempMED - DD Bio Splint P
Common Name	Crown and Bridge, Temporary, Resin
Classification Name	Temporary crown and bridge resin
Regulation Number	21 CFR 872.3770
Classification Product Code	EBG, MQC
Panel	Dental
Classification	Class II
Predicate Device	K150432: Union Dental S.A. Idodentine (Dental Polymer Blank)

Indications for Use	DD medical polymers are indicated for temporary (≤ 12 months) crowns, bridges and bite splints. Applications include both anterior and posterior structures.
Device Description	DD medical polymers, made from medical grade, are industrially polymerized, pre-colored or clear dental milling blanks designed for milled fabrication of temporary anterior and posterior crowns and bridges (tooth-colored variants) or bite splints (clear variant) on dental CAD/CAM systems.
Technological characteristics	The technologic characteristics are highly similar as demonstrated in performance testing and in chemical composition; both devices are composed primarily of polymethylmethacrylate, while the amount and percentage of color oxides in the submission device varies from the predicate.
Comparison of Required Technology Characteristics	The following table shows a summary of the technological characteristics of DD medical polymers compared to the predicate device.

Comparison of Required Technology Characteristics		
Feature	**Submission device**	**Predicate device**
Trade name	*DD medical polymers*	*Idodentine Disc*
510(k)	K153490	K150432
Product code	EBG, MQC	EBG
Regulatory class	Class II	Class II
Manufacturer	Dental Direkt GmbH	Union Dental S.A.
Intended use	DD medical polymers are indicated for temporary (≤ 12 months) crowns, bridges and bite splints. Applications include both anterior and posterior structures.	Acrylic polymer blank particularly suitable for making removable or temporary dental structures such as crowns and bridges using milling technology using CAD/CAM. Indications - Temporary anterior and posterior crowns - Temporary anterior and posterior bridges with up to two adjacent pontics Maximum recommended usage period: 12 months - Removable structures for dentures (denture bases) - Removable structures for therapeutic restorations (bite splints or occlusal splints)
Max. application time	12 months	12 months
Technology	Blank for dental CAD/CAM machining	Blank for dental CAD/CAM machining
Shape	Disc	Disc or block
Shade	VITA-shades, clear	VITA-shades, clear, pink
Comparison of Required Technology Characteristics		
Raw material	PMMA	PMMA
Chemical composition [Units]		
Material base	> 99.0 [wt%] (Polymethyl methacrylate)	Polymethyl methacrylate
Coloring oxides	≤ 1.0 [wt%]	Not specified
Physical characteristics [Units]		
Performance testing	Tested according to DIN EN ISO 20795-1 and ISO 10477	Tested according to DIN EN ISO 20795-1 and ISO 10477
Biocompatibility	EN ISO 10933-1, -5	EN ISO 10933-1, -5,

Discussion of Tests Performed

Clinical Tests

Dental Direkt GmbH did not conduct, nor rely upon, clinical tests to determine substantial equivalence.

Non Clinical Tests

Non-clinical testing according to the following standards was performed in order to validate the product against the company's specified design requirements:

- EN ISO 10993-1 (biological compatibility) and EN ISO 10993-5 (cytotoxicity):

Finished *DD medical polymer* products in all variants were tested by an accredited testing laboratory (GLP-certified) with respect to biocompatibility. The laboratory certified that "the insolubility is in compliance with the requirements of the standard. There is no evidence that effects hazardous to the patient will arise by release of leachable ingredients/contaminants".

- DIN EN ISO 20795-1:2013: Dentistry - Base polymers - Part 1: Denture base polymers
- ISO 10477:2004: Dentistry – Polymer-based Crown and Bridge Materials

	Requirements acc. to DIN EN ISO 20795-1 / ISO 10477:				
Requirement	**Required Value** (ISO 20795-1)	**Required Value** (ISO 10477)	**Value Subm. Device**	**Value Predicate Device**	**Passed / Failed**
Flexural strength [MPa]	≥ 65	≥ 50	≥ 75	90	Passed
Flexural modulus [MPa]	≥ 2000	-	2800 (± 200)	not specified	Passed
Residual MMA monomer [%]	≤ 2.2	-	0.4	1.4	Passed
Water sorption [µg/mm³]	≤ 32	≤ 40	≤ 23	23	Passed
Solubility [µg/mm³]	≤ 1.6	≤ 7.5	0.2	0.0	Passed

Substantial Equivalence Conclusion	The small difference in the indication of the predicate device is due to a bigger range of shades available. The missing pink variant by Dental Direkt is the only reason why the application field of denture bases is not contained in the indication of DD medical polymers. The restriction regarding the maximum amount of pontics for bridge constructions is listed as contraindication in the IFU of DD medical polymers. In summary neither the fundamental intended use nor the safety and effectiveness of the product is influenced by the deviation of the indication of submission device and predicate device. Based on comparison of technology, including composition and performance testing, biocompatibility testing, and highly similar indications for use, DD medical polymers are substantially equivalent to Idodentine (K150432).