DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 19, 2016

Dentalplus GmbH
Mr. Ralf Rueth
CEO
Kohlgrub 5
Samberg, 83122 DE
GERMANY

Re: K152215
Trade/Device Name: Dentalos Plus Mono, Dentalos Plus Multicolor
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: December 4, 2015
Received: December 24, 2015

Dear Mr. Rueth:

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" (21CFR 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,

for 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: K152215

Device Name: DENTALOS PLUS MONO
DENTALOS PLUS MULTICOLOR

Indications For Use:

DENTALOS PLUS discs are milling blanks consisting of Polymethylmethacrylate (PMMA) and designed for the fabrication of long-term temporary crown and bridgework. They are machined by use of the CAD/CAM technique.

DENTALOS PLUS discs are recommended for manufacturing substructures of single tooth crowns and bridgeworks with up to two pontics.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (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)

K152215

510[k] Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	DentalPlus GmbH
Submitter Address	Kohlgrub 5, D-83122 Samerberg, Germany
Phone Number	+49-8032-9892007
Fax Number	+49-8032-9882790
Contact Person	Ralf Gerschütz Rüth
Date summary was prepared	December 4, 2015
Device Trade Name(s)	DENTALOS PLUS MONO DENTALOS PLUS MULTICOLOR
Classification Name	Temporary Crown and Bridge Resin
C.D.R. section number	872.3770
Product Code	EBG
Regulatory Class	Class II
Predicate Devices	K122025 BRIGHTGLASS BRIGHTGLASS M
Device Description	DENTALOS PLUS discs are milling blanks composed of hot cured polymethylmethacrylate (PMMA). They are intended to be used by dental professionals e.g. dental technicians for the fabrication of long-term temporary crowns and bridgeworks as custom-made restorations for the sole use of a particular patient. These restorations are designed virtually by dental technicians using the CAD technology on the basis of intraoral scans or scans from impressions and/or models. The designed restorations can thereafter be machined in all appropriate CAM Milling Centers out of DENTALOS PLUS Discs. In a further step the milled workpiece can be individually characterized with veneering materials and polished for to improve the aesthetic appearance of the finished restoration. DENTALOS PLUS discs are offered as monochrome discs (DENTALOS PLUS MONO) in nine different shades and as multicolored discs (DENTALOS PLUS MULTICOLOR) in five shades, all discs in different thicknesses.

Indications for Use

DENTALOS PLUS Discs are milling blanks consisting of polymethylmethacrylate (PMMA) and are designed for the fabrication of long-term temporary crown and bridgework using the CAD/CAM technique.

DENTALOS PLUS Discs are recommended for manufacturing substructures of single tooth crowns and bridgework with up to two pontics.

Performance Testing

In order to demonstrate comparability of DENTALOS PLUS blanks to the predicate devices DENTALOS PLUS blanks a series of testing was performed – in particular tensile strength, elastic limit, bending strength, e-module, water solubility and water absorption.

The results of this testing showed that the physical properties and performance of the subject device are comparable to the identified predicate devices.

The standards used for performance testing are ISO 10477:2004, ISO 527-1:2012, and ISO 572-2:2012.

Summary of Technological Characteristics

Devices	DENTALOS PLUS MONO DENTALOS PLUS MULTICOLOR	BRIGHTGLASS BRIGHTGLASS M
510(k) Number	K152215	K122025
Manufacturer	DentalPlus GmbH	KTK Medical Supplies GmbH
Trade Name [s]	DENTALOS PLUS MONO Blanks DENTALOS PLUS MULTICOLOR	BRIGHTGLASS BRIGHTGLASS M
Shape [delivery form]	Blanks (discoidal)	Blanks (discoidal)
Classification Product Code	872.3770 EBG	872.3770 EBG
Intended Use	DENTALOS PLUS devices are milling blanks consisting of polymethylmethacrylate (PMMA) and designed for the fabrication of long-term temporary crown and bridgework using the CAD/CAM technique. DENTALOS PLUS blanks are recommended for manufacturing substructures of single tooth crowns and bridgework with up to two pontics.	BRIGHTGLASS Discs are milling blanks consisting of polymethylmethacrylate (PMMA) and designed for the fabrication of long-term temporary crown and bridgework using the CAD/CAM technique. BRIGHTGLASS Discs are recommended for manufacturing substructures of single tooth crowns and bridgework with up to two pontics.
Intended Customers	Professional dental technicians	Professional dental technicians
Further Processing	Milling in CAM milling centers using CAD/CAM technique	Milling in CAM milling centers using CAD/CAM technique
Types	monochrome blanks transitional shaded blanks different shades	monochrome blanks transitional shaded blanks different shades

Devices	DENTALOS PLUS MONO DENTALOS PLUS MULTICOLOR		BRIGHTGLASS BRIGHTGLASS M	
Fabrication method	Granulate material (resin) plasticized through heat and sprayed into a form under high pressure		Granulate material (resin) plasticized through heat and sprayed into a form under high pressure	
Material Composition	hot cured Polymethylmethacrylate (PMMA) > 99,9 % Different pigments – total percentage < 0,1 %		hot cured Polymethylmethacrylate (PMMA) > 99,9 % Different pigments – total percentage < 0,1 %	
physical properties	e module	3370 MPA	e module	3370 MPA
	tensile strength	76,3 MPA	tensile strength	76,3 MPA
	Elastic Limit	70 MPA	Elastic Limit	70 MPA
	Bending strength	106 MPA	Bending strength	106 MPA
	water absorption	19,36 µg/m³	water absorption	19,36 µg/m³
	water solubility	< 1µg/m³	water solubility	< 1µg/m³

The only difference between the subject device and the noted predicate device is the addition of further shades of color based on slight variations of the pigments within a range of 0,1 % totally according to their type and percentage.

Substantially Equivalence

The information discussed above demonstrates that DENTA- LOS PLUS discs are substantially equivalent to the predicate dental device DENTALOS PLUS Discs.

Both devices are polymethylmethacrylates (PMMA).

Both devices have identical indications for use.

Both devices have comparable technical, physical, chemical, and biological properties and characteristics.

Both devices have the same aesthetic, prophylactic and diagnostic function.

The thermoplastic manufactured DENTALOS PLUS disks shows like the predicate device an extreme high homogeneity and by the high surface density a major bending strength and breaking resistance.

Conclusion

The information discussed above demonstrates that the DEN- TALOS PLUS discs are substantially equivalent to the predicate devices.