October 27, 2020

DETAX GmbH & Co.KG
% Jan-Paul Van Loon
Consultant
Qserve Consultancy BV
Utrechtseweg 310 - Bldg. B42
Arnhem, 6812 AR NETHERLANDS

Re: K200273
Trade/Device Name: FREEPRINT temp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: September 30, 2020
Received: October 1, 2020

Dear Jan-Paul Van Loon:

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)*

K200273

Device Name
FREEPRINT temp

Indications for Use *(Describe)*

FREEPRINT temp 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.

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.

510(k) Summary

I SUBMITTER	
Submitter Name:	DETAX GmbH & Co.KG.
Submitter Address:	Carl-Zeiss-Stasse 4 D-76275 Ettingen, Germany
Phone Number:	+49 (0)7243/510-138
Contact Person:	M. (Markus) Stratmann
Date Prepared:	October 26, 2020
II. DEVICE	
510(k) number	K200273
Device Trade Name:	FREEPRINT temp
Common Name	Temporary crown and bridge resin
Classification	21 CFR 872.3770
Classification Name	Temporary crown and bridge resin
Product Code:	EBG
Review Panel:	Dental
III. PRIMARY PREDICATE DEVICE	K180657, Resin for Temporary Crown & Bridge, Dentis Co., Ltd.
IV. DEVICE DESCRIPTION	
Description:	FREEPRINT temp is a family of light-cured-component materials for the Digital Light Processing (DLP)-printing of temporary Crowns & Bridges (C&B) material. It is stored in 500 and 1000ml HDPE bottles. It contains materials with colours of A1, A2, and A3 based on the shade guide. This Product is a liquid photo-curable material that is polymerized by UV laser at 385nm. It can be used to make a tooth model with a photo-curable polymer that is cured by ultraviolet light. The liquid UV curing resin is cured at a specific wavelength (385nm) by the photo-initiator contained in the resin. This device can be manufactured with 3D stereolithographic printer with 385nm wavelength lightsource. Curing in a 3D printer is related to the conditions of the printer equipment and is typically 50µm in thickness. Output resolution ranges from 34µm to 75µm on the x, y axis.
Physical Description:	FREEPRINT temp: dimethacrylate based resin 1-component system. Processed (3D printed) using 385nm light source.
V. INTENDED USE / INDICATION FOR USE STATEMENT	FREEPRINT temp 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.

VI. SUMMARY OF PERFORMANCE DATA AND DESIGN CONTROLS:

Bench testing was carried out on the following characteristics:

- Printers validation

Four printers are validated for processing (3D printing) using FREEPRINT temp. Additional printers post-510(k)-clearance will be added to the labelling by means of the Quality Systems and within the validation plan presented in this 510(k).

Referenced Standards and Performance Testing:
Performance testing confirmed the FREEPRINT temp demonstrated performance to the acceptance criteria referred to ISO 10477 and ISO 7491.
The composition of FREEPRINT temp exhibits sufficient strengths and performances in all intraoral conditions and will sufficiently resist compressive & tensile loads, hardness, water sorption and solubility.

Biocompatibility testing:
FREEPRINT temp in all variants were tested with respect to biocompatibility according to ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11 and ISO 10993-17, taking ISO 7405 into account. The results showed that the insolubility is in compliance with the requirements of the standard. There is no evidence that hazardous effects will arise by leachable ingredients/contaminants.

Clinical Tests:
No clinical tests were performed with FREEPRINT temp

VII. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE DEVICES

FREEPRINT temp has been compared to the Primary Predicate device, Resin for Temporary Crown & Bridge, Dentis Co., Ltd. (K180657). Details are provided in Table 1 below.

Comparison of the Indications for Use and Technological Characteristics:

FREEPRINT temp has a similar Indications for Use statement as the predicate device.
FREEPRINT temp has the following similarities in technological characteristics as the predicate device:

- Same type of materials (chemical composition) that form the basis for the device used.
- Same technology, both are light curing resins that are cured in a 3D printer.
- Similar mechanical and physical properties. Although the devices use a different wavelength for polymerization (curing method), both devices meet the requirements of the same performance and biocompatibility standards, therefore the devices can be considered equivalent.

Table 1: Summary of Technological Characteristics of FREEPRINT temp and the Predicate device

Feature	Primary Predicate device	FREEPRINT temp		
510(k) Number	K180657	K200273		
Manufacturer	Dentis Co., Ltd..	DETAX GmbH & Co.KG		
Trade name	Resin for Temporary Crown & Bridge	FREEPRINT temp		
CFR Regulation Number	872.3770, Temporary crown and bridge resin. (a) Identification. A temporary crown and bridge resin is a device composed of a material, such as polymethylmethacrylate, intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.	872.3770, Temporary crown and bridge resin. (a) Identification. A temporary crown and bridge resin is a device composed of a material, such as polymethylmethacrylate, intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.		
Product Code	EBG	EBG		
Classification	Class II, Performance standards	Class II, Performance standards		
Classification Panel	Dental	Dental		
Intended Use	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.	FREEPRINT temp 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.		
Technological Characteristics			Same / different technological characteristics	Impact on safety and effectiveness
Acrylic Resin	Light-cure resin	Light-cure resin	same	no
Chemical Characterization	Methacrylate-based resins with photo-initiator, filler and pigments	Liquid, light-curing (meth)acrylate-based one-component material	Same type of materials	No, based on performance testing & Bio-compatibility testing
Polymerization (Curing) method	Visible light, 405 nm	Visible light, 385 nm	Same technology, different wave length	No, based on performance testing & Bio-compatibility testing
Fabrication of Denture Base	Automated printing of resin in multiple layers, each light-cured before adding next layer, with post curing	Automated printing of resin in multiple layers, each light-cured before adding next layer, with post curing	same	no

	in light chamber	in light chamber		
Post Curing	Visible light-curing unit	Visible light-curing unit	same	no
Teeth assemble	Bonding after polymerization	Bonding after polymerization	same	no
Residual methyl methacrylate monomer	Not applicable, the material does not contain methyl methacrylate Total methyl methacrylate monomers < 0.1% mass fraction	Not applicable, the material does not contain methyl methacrylate Total methyl methacrylate monomers < 0.1% mass fraction	NA	NA
Performance standards	ISO 10477 Third edition	ISO 10477 Third edition	Same	no
Biocompatibilty	ISO 7405:2008/A1:2013 ISO 10993-1:2009/C1:2010 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017	ISO 7405:2014 ISO 10993-1:2018 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-10:2013 ISO 10993-11:2017	similar	Currently Recognized Consensus Standards Applied

VIII. CONCLUSION OF SUBSTANTIAL EQUIVALENCE

FREEPRINT temp and the predicate have the same intended use and similar technological characteristics.

The results of the performed tests show that FREEPRINT temp meets the requirements mentioned in the applicable standards and confirm that the device performs similarly to the predicate device.

It is therefore concluded that FREEPRINT temp performs as intended and is substantially equivalent to the predicate device.