Dear Hwi Joon Park:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3
Digitally signed by Mary S. Runner -S3
Date: 2018.12.07 10:21:47 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
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.
### 510(k) Summary

| Submitter | Dentis Co., Ltd.  
99, Seongseoseo-ro, Dalseo-gu, Daegu, 42718 Republic of Korea  
Phone: +82-53-583-2804  
Fax: +82-53-283-2806 |
|---|---|
| Contact Person | HWI JOON PARK  
8141 Lampson Ave. #4, Garden Grove, CA 92841, USA  
Phone: +1-972-800-0044  
Fax: +1-210-899-0079 |
| Submission Date | Mar 08, 2018 |
| Trade / Proprietary name | Resin for Temporary Crown & Bridge |
| Common / Usual Name | Crown and Bridge, Temporary, Resin |
| Classification Name | Temporary Crown and Bridge Resin |
| Classification Code | EBG |
| Regulatory Class | Class II 872.3770 |
| Predicate Device | DeltaMed GMBH  
e-Dent Temporary Resin and Extra-Oral Curing System  
(K102776, Feb 18, 2011 - Primary Predicate) |
| Description of Device | The Resin for Temporary Crown & Bridge is made by Methacrylate Oligomer based on the Urethane Acrylate Oligomer with 0.01~0.1wt% inorganic filler. It has stored in a brown 1000ml of HDPE bottle. It contains materials with colors of A2 based on the shade guide.  
This Product is a liquid photo-curable material that is polymerized by UV laser at 405nm. 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 (405nm) by the photo-initiator contained in the resin.  
Curing in a 3D printer is related to the conditions of the printer equipment, and is typically 0.1 to 0.010mm in thickness, and is output at a resolution of 0.1 to 0.03 mm on the x, y axis. This device should use ZENITH 3D Printer equipment using UV light source of Dentis Co., Ltd., and it is possible to produce three dimensional printed matter by curing lamination step by step a thicknesses of 100, 50 and 16$\text{um}$. |
| Indication for 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. |
| Comparison of Technological Characteristics with the Predicate Devices | **Indication for Use**  
The Resin for Temporary Crown & Bridge and the predicate device have similar indications for use statements. Limitation on the duration of the subject device was intended to ensure the performance of subject device by narrowing down the allowed terms of its prosthetic use. Such difference is not critical to the intended use of the subject device. Therefore it doesn’t affect the safety and effectiveness of the device when used as labeled. |
### Technological Characteristics
The subject device is a polymer that changes its properties when exposed to UV light. It conforms into a hardened polymeric material through a process called curing. Temporary dental restoration using resin is technologically useful applications for dental treatment.

Above technological characteristics of the subject device is identical to the predicate device.

### Materials
The subject device is composed of the each raw material whose safety were evaluated by suppliers and the results were indicated on MSDS. Moreover, the Resin for Temporary Crown & Bridge was evaluated for biocompatibility based on ISO 10993.

### Clinical Tests
The Resin for Temporary Crown & Bridge and the cited predicate device were not conducted clinical tests to determine substantial equivalence.

### Non-clinical Tests
Non-clinical testing was performed in order to validate the product against the company’s specified design requirement.

The Resin for Temporary Crown & Bridge in all variants were tested with respect to biocompatibility according to EN ISO 10993-3, EN ISO 10993-5, EN ISO 10993-10 and EN ISO 10993-11. 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 leachable ingredients/contaminants.

The composition of the Resin for Temporary Crown & Bridge exhibits sufficient strengths and performances in all intraoral conditions and will sufficiently resist compressive & tensile loads, hardness, water sorption and solubility.

### Sterilization
The Resin for Temporary Crown & Bridge and the cited predicate device are provided non-sterile.

### Performance Specification
Performance testing confirmed the Resin for Temporary Crown & Bridge demonstrated equivalent or better performance to the predicate device or acceptance criteria referred to ISO 10477.

### Conclusion
It is adequate for the intended use and it shows that there are no significant differences between the Resin for Temporary Crown & Bridge and the predicate device currently being marketed that would adversely affect the use of the product. Any differences in technological characteristics do not raise new issues of safety or efficacy.

Therefore, conclusions drawn from testing demonstrate that the Resin for Temporary Crown & Bridge is substantially equivalent in performance to predicate device.