December 8, 2021

Arum Dentistry Co., Ltd
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, California 92620

Re: K210817
Trade/Device Name: C&B 5.0 Hybrid
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: October 11, 2021
Received: November 08, 2021

Dear Priscilla Chung:

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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210817

Device Name
C&B 5.0 Hybrid

Indications for Use *(Describe)*
C&B 5.0 Hybrid resin is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges. The fabricated temporary crowns or bridges are an alternative to preformed temporary crowns or bridges and require digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment.

Type of Use *(Select one or both, as applicable)*

[X] 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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510(k) Summary
(K210817)

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Oct 12, 2021

1. Applicant / Submitter:

Arum Dentistry Co., Ltd.
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South Korea
Tel. +82-42-935-3644

2. Submission Correspondent:

Priscilla Chung
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1150 Roosevelt STE 200,
Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	C&B 5.0 Hybrid
Common Name:	3D temporary crown and bridge resin
Classification Name:	Temporary crown and bridge resin
Classification:	Class II, 21 CFR 872.3770
Classification Product Code:	EBG

4. Predicate Device:

Resin for Temporary Crown & Bridge (K180657) by Dentis Co., Ltd.

5. Device Description:

The C&B 5.0 Hybrid is made from 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. The subject device is liquid photo-curable material that is polymerized by UV laser at 405nm. 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 DLP/LCD 3D Printer equipment using UV light source and it is possible to produce three dimensional printed matter by curing lamination step by step a thicknesses of 100, 50 and 16 ㎛.

6. Indications for Use:

The C&B 5.0 Hybrid 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.

7. Performance Data (Non-Clinical):

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

Test	Test Item	Referenced Standard
Shelf-Life Validation Tests	Visual inspection	-
	Packaging	ISO 10477
	Flexural strength	ISO 10477
Biocompatibility Tests	Cytotoxicity	ISO 10993-5
	Sensitization	ISO 10993-10
	Acute Toxicity	ISO 10993-11
	Oral Mucosal Irritation	ISO 10993-10
Performance Tests	Visual Inspection	-
	Packaging	-
	Capacity	-
	Color Consistency	-
	Color Stability	ISO 10477
	Flexural Strength	ISO 10477
	Water Absorption	ISO 10477
	Solubility Test	ISO 10477

8. Substantial Equivalence

The following table compares technological and other characteristics of the subject and a predicate device.

	Subject Device	Predicate Device	Comparison
Applicant	Arum Dentistry Co., Ltd.	Dentis Co., Ltd	-
Trade Name	C&B 5.0 Hybrid	Resin for Temporary Crown & Bridge	-
510(K) No.	K210817	K180657	-
Regulation Name	Denture Relining, Repairing, Or Rebasing Resin	Denture Relining, Repairing, Or Rebasing Resin	same
Product Code	EBG	EBG	same
Class	Class II	Class II	same
Device Identification	Light-cured resin	Light-cured resin	same
Indications for Use	The C&B 5.0 Hybrid 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.	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.	same
Materials of Use	Titanium dioxide	Titanium dioxide	similar
	Trimethylolpripanetrimethacrylate	Ethyl acrylate	
	Diphenyl phosphine oxide	Diphenyl phosphine oxide	
	Silicon Oxide	Methyl methacrylate	
	Urethane Dimethacrylate	Urethane methacrylate	
	Pigments: Yellow	Cesium oxide (Pigments)	
	Pigments: Red		
	Pigments: Black		
Device state	Pre-mixed liquid resin provided in a container	Pre-mixed liquid resin provided in a container	same
Polymerization (Curing) Method	Visible light	Visible light	same
Fabrication of Denture Base	CAD/CAM additive printing process	CAD/CAM additive printing process	same
Post Curing	Visible light-curing unit	Visible light-curing unit	same
Product State	Pre-mix resin	Pre-mix resin	same
Teeth Assemble	Bonding	Bonding	same
Sterilization	None	None	same
Biocompatibility	Meets ISO 10993	Meets ISO 10993	same
Performance Test	Meets ISO 10477	Meets ISO 10477	same

The subject device has the same indications for use as the predicate device. Both devices are methacrylate-based resin and uses the same technology of CAD/CAM system to make the final prosthetic appliances. The major differences would be raw material compositions. We have

performed the biocompatibility and performance tests to support that the subject device is substantially equivalent to the predicate device despite this difference.
Based on the test results submitted here in, we conclude that the subject device is substantially equivalent to the predicate device.

9. Conclusion:

Based on the testing results, Arum Dentistry Co., Ltd. concludes that the C&B 5.0 Hybrid is substantially equivalent to the predicate devices.