September 11, 2024

Arum Dentistry Co., Ltd.
Boyeon Lim
Assistant Manager
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
Korea, South

Re: K232559
Trade/Device Name: C&B NFH Hybrid
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBG
Dated: August 9, 2024
Received: August 9, 2024

Dear Boyeon Lim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232559

Device Name
C&B NFH Hybrid

Indications for Use *(Describe)*

The C&B NFH Hybrid is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The C&B NFH Hybrid material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of C&B NFH Hybrid requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K232559

Submitter

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Device Information

- Trade Name: C&B NFH Hybrid
- Classification Name: Tooth shade resin material (21 CFR 872.3690), Crown and Bridge, Temporary, Resin (21 CFR 872.3770)
- Product Code: EBF, EBG
- Panel: Dental
- Device Class: Class II
- Date Prepared: 09/11/2024

Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K202846, TERA HARZ by Graphy Inc.

General Description

The C&B NFH Hybrid is a light-cured, methacrylate oligomer based polymerizable resin used by dentist or dental technician for the CAD/CAM manufacturing of indirect restorative for both anterior and posterior restorations, including occlusal surfaces, such as temporary or permanent crowns and bridges, inlays, onlays and veneers. Methacrylate based resin is known materials, commonly used in the dental industry for fixed and removable prosthetic devices due to their physical-chemical, mechanical and biocompatible properties.

For the C&B NFH Hybrid, the bonding agent needed to affix the device to performed teeth.

Dental Cement

K193260, U-Cem Premium & MAZIC Cem by Vericom Co., Ltd.

Specific Manufacturing considerations

1. Digital file
   - File format: STL file
   - File size should be upload-able in the 3D printer operation software

2. Printer
   - Laser wavelength: 385 nm ~ 405 nm
   - Light source: Photopolymerization
   - Build speed: 50 ㎛ layer height (1.4 Second), 100 ㎛ layer height (1.9 seconds)
   - Build path: line drawing path or surface layer drawing path

3. Printing parameters

Printer Model	Layer Thickness (micron)	Recommended orientation angle (degree)	Support point size(mm)	Support density
ARUM LCD	50-100	45°	0.2	50%

4. Environmental conditions
   - Temperature: 18 – 30 °C
   - Relative Humidity: 30 – 90 %

Indication for Use

The C&B NFH Hybrid is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The C&B NFH Hybrid material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of C&B NFH Hybrid requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.

Summaries of Technology Characteristics

The following table compares the C&B NFH Hybrid to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

	Subject Device	**Predicate Device**
Manufacturer	ARUM DENTISTRY Co., Ltd.	Graphy Inc.
Device Name	C&B NFH Hybrid	TERA HARZ
510(k) Number	N/A	K202846
Intended Use/ Indications for use	C&B NFH Hybrid is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The C&B NFH Hybrid material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of C&B NFH Hybrid requires a computer-aided and Manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.	TERA HARZ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The TERA HARZ material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of TERA HARZ requires a computer-aided and Manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.
Manufacturing Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM
Chemical composition	Trimethylolpropane Trimethacrylate Diphenyl phosphine Oxide Urethane Dimethacrylate Titanium dioxide Pigments	Polyurethane Resin; Methacrylate; Dimethacrylate; Phosphine oxide; Butylated Hydroxytoluene Pigments

Sterilization	Non-Sterile	Non-Sterile
Flexural Strength (≥50 MPa; ISO10477 ≥100Mpa; ISO 4049)	Avg. 114.32 MPa	Avg. 148.73 MPa
Water sorption (≤40 μg/mm^3)	Avg. 31.32 μg/mm^3	Avg. 13.03 μg/mm^3
Solubility (≤7.5 μg/mm^3)	Avg. 5.59 μg/mm^3	Avg. 1.00 μg/mm^3
Material Shades	A1 ~ A3	A1 ~ A3
Substantial Equivalent Discussion	**1. Similarities** The subject and predicate or reference devices are very similarities in they are all polymer resins. The specifications of flexural strength, water sorption and solubility are in the same range. This minor variance does not introduce additional safety or efficacy concerns. Both devices meet requirements from ISO 10477:2020, Dentistry – Polymer-based crown and veneering materials. and ISO 4049:2013, Dentistry – Polymer-based restorative materials **2. Differences** Compared with the primary predicate, the slight differences in chemical composition do not change the intended use of the subject, predicate and reference devices to be used in the fabrication of dental prostheses. The material is an alternative to traditional heat cured and auto polymerization resins.	

Non-Clinical Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Performance Testing

The C&B NFH Hybrid is very similar to the predicate devices and demonstrate substantial equivalence to predicate devices K202846. An analysis for subject device compared to the predicate device show C&B NFH Hybrid and the predicate device meet all two devices share the same product code, meet the requirements, and all two are biocompatible. In addition, an analysis for subject device compared to the predicate device show C&B NFH Hybrid and predicate resin meet the requirements ISO 10477:2020, Dentistry – Polymer-based crown and veneering materials. and ISO 4049:2013, Dentistry – Polymer-based restorative materials.

Biocompatibility

The biocompatibility discussion was conducted. The C&B NFH Hybrid uses the Dimethacrylate – based resins and this material has been tested and shown to be compliant with the following standards:

- ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-12:2021, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for irritation

Shelf-Life

The tests to validate the Shelf-Life of the device through the proposed Shelf-Life were conducted using the accelerated aging method in accordance to ASTM F1980 and test results validated 2 years Shelf-Life.

Conclusion

The C&B NFH Hybrid is very similar to both predicate devices and demonstrate substantial equivalence to predicate device K202846.

An analysis for subject device compared to the predicate device show the C&B NFH Hybrid and the TERA HARZ meet all two devices share the same product code, met the requirements, and all two are biocompatible.

In addition, an analysis for subject device compared to the predicate device show the C&B NFH Hybrid and the TERA HARZ meet the requirements for ISO 10477:2020, Dentistry – Polymer-based crown and veneering materials and ISO 4049:2013, Dentistry – Polymer-based restorative materials. Overall, the subject device is substantially equivalent to the Predicate device.