September 23, 2022

HDI, Inc.
Taekyou Kim
CEO
A-1504, 14, Sagimakgol-ro, 45 Beon-gil, Jungwon-gu
Seongnam-si, Gyeonggi-do 13209
SOUTH KOREA

Re: K213339
Trade/Device Name: DENU Composite Resin, DENU Flow Resin
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: July 22, 2022
Received: July 26, 2022

Dear Taekyou Kim:

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

4. INDICATION FOR USE STATEMENT

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)*
K213339

Device Name
DENU Composite Resin, DENU Flow Resin

Indications for Use *(Describe)*
DENU Composite Resin is indications for use in:
- Direct anterior and posterior restorations
- Core buildup
- Splinting
- Indirect anterior and posterior restorations including inlays, onlays and veneers

DENU Flow Resin is indications for use in:
- Class III restorations
- Class V restorations
- Small Class I restorations (non stress-bearing restorations)
- Pit and fissure sealing in molars and premolars
- Repair of small defects in esthetic indirect inlays
- Base/liner under direct restorations

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.

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FORM FDA 3881 (6/20) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

5. 510(k) SUMMARY

K213339

510(k) Summary

Date: July 22, 2022

1. SUBMITTER

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2. DEVICE

·Trade Name: DENU Composite Resin, DENU Flow Resin
·Common Name: Tooth shade resin material
·Classification Name: Material, Tooth shade, Resin
·Regulation Number 872.3690
·Class: 2
·Classification Product Code:
DENU Composite Resin
Primary product code: EBF
DENU Flow Resin
Primary product code: EBF
Secondary product codes: EBC, EJK

3. CLEARED DEVICE (PREDICATE DEVICE)

K083610, FILTEK SUPREME ULTRA UNIVERSAL RESTORATIVE, 3M ESPE
K100235, FILTEK SUPREME ULTRA FLOWABLE RESTORATIVE, 3M ESPE

4. DEVICE DESCRIPTION

DENU Composite Resin is light-cured composite resin which can be used in anterior and posterior teeth. This is classified into type 1, class 2, group 1 according to 4, ISO 4049:2019.

DENU Flow Resin is light-cured flowable composite resin which can be used in anterior and posterior teeth. This is classified into type 1, class 2 group 1 according to 4, ISO 4049:2019.

5. INDICATIONS FOR USE

DENU Composite Resin is indicated for use in:

- Direct anterior and posterior restorations
- Core buildup
- Splinting
- Indirect anterior and posterior restorations including inlays, onlays and veneers

DENU Flow Resin is indicated for use in:

- Class III restorations
- Class V restorations
- Small Class I restorations (non stress-bearing restorations)
- Pit and fissure sealing in molars and premolars
- Repair of small defects in esthetic indirect inlays
- Base/liner under direct restorations

6. PERFORMANCE TESTING (NON-CLINICAL)

The following test articles were tested based on the referenced standard. All the test results met the preset test criteria.

- ISO 4049 – Sensitivity of ambient light, Depth of cure, Flexural Strength, Water Sorption, Solubility, Radio-opacity, Color/Color Stability
- ISO 10993-3 - Genotoxicity
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Skin sensitization, Oral mucosa irritation
- ISO 10993-11 - Acute systemic toxicity

7. SUBSTANITAL EQUIVALENCE

DENU Composite Resin

Descriptive Information	New device	Predicate device	Discuss/Justify the Differences
510(k) Number	New	K083610	-
Trade Name	DENU Composite Resin	Filtek™ Supreme Ultra Universal Restorative	-
Manufacturer	HDI, Inc.	3M ESPE	-
Common Name	Tooth shade resin material	Tooth shade resin material	Equivalent
Device Class	2	2	Equivalent
Product Code	EBF	EBF	Equivalent
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	Equivalent
Device Description	DENU Composite Resin is light-cured composite resin which can be used in anterior and posterior teeth. This is classified into type 1, class 2, group 1 according to 4, ISO 4049:2019.	3M™ ESPE™ Filtek™ Universal Restorative material is a visible-light activated, restorative composite designed for use in anterior and posterior restorations	Equivalent
Intended Use(including the indications for use)	- Direct anterior and posterior restorations - Core buildup - Splinting - Indirect anterior and posterior restorations including inlays, onlays and veneers	- Direct anterior and posterior restorations (including occlusal surfaces) - Core build-ups - Splinting - Indirect restorations including inlays, onlays and	Equivalent

		veneers	
Intended user	Dental professional	Dental professional	Equivalent
Composition of Materials	BISGMA UDMA TEGDMA Ba glass Silane Camphorquinone Ethyl 4-dimethylaminobenzoate Titanium(IV) oxide Yellow ferric oxide Iron(III) oxide Iron(II,III) oxide	BISGMA UDMA TEGDMA BISEMA-6 PEGDMA Silane treated ceramic Silane Treated Silica Silane Treated Zirconia Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Similar
Applicable standards	ISO 4049 ISO 10993	ISO 4049 ISO 10993	Equivalent
Physical properties			
Compressive strength	187.4(46) MPa	DEB Shade - 370.56 (15.13) MPa T Shade - 394.01 (25.05) MPa	Both met acceptance criteria
Flexural strength	135.74(11.72) MPa	DEB Shade - 165.14 (13.59) MPa T Shade - 157.98 (8.16) MPa	Both met acceptance criteria
Elastic modulus	7950.5(464.6) MPa	DEB Shade - 11348 (271) MPa T Shade - 9180 (431) MPa	Both met acceptance criteria

Depth of cure	A0 - 3.86(0.15) mm UO - 3.43(0.11) mm	2.60(0.02) mm	Both met acceptance criteria
Filler particle size distribution	Silica filler 16nm Glass filler 4 ㎛	Silica filler - non-agglomerated/non-aggregated : 20 nm Zirconia filler -non-agglomerated/non-aggregated : 4 to11 nm zirconia/silica cluster filler - aggregated : comprised of 20 nm silica and 4 to 11 nm zirconia particles	Both met acceptance criteria
Surface hardness	43.86(3.02) KHN	78.664(0.68) KHN	Both met acceptance criteria
Radio-opacity	3.2 mmAl	2.1(0.0) mmAl	Both met acceptance criteria
Water sorption	18.48(0.84) µg/mm3	33.1(2.1) µg/mm3	Both met acceptance criteria
Solubility	0.82(0.76) µg/mm3	1.0(0.7) µg/mm3	Both met acceptance criteria
Curing time	20 sec	Dentin/Enamel/Translucent shade(Increment depth 2.0mm) : 20 sec Dentin, A6B, B5B shade (Increment depth 1.5mm) :	Both met acceptance criteria

		40 sec	
Intensity for curing	400mW/㎠ (Halogen or LED)	400 mW/cm2 (Halogen or LED)	Equivalent
Wavelength for curing	400-500 nm (Halogen or LED)	400-500 nm (Halogen or LED)	Equivalent
Sterile	Non-sterile	Non-sterile	Equivalent
Shelf Life	3 years	3 years	Equivalent

DENU Flow Resin

Descriptive Information	**New device**	**Predicate device**	**Discuss/Justify the Differences**
510(k) Number	New	K100235	-
Trade Name	DENU Flow Resin	Filtek™ Supreme Ultra Flowable Restorative	-
Manufacturer	HDI, Inc.	3M ESPE	-
Common Name	Tooth shade resin material	Tooth shade resin material	Equivalent
Device Class	2	2	Equivalent
Product Code	EBF	EBF	Equivalent
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	Equivalent
Device Description	DENU Flow Resin is light-cured flowable composite resin which can be used in anterior and posterior teeth. This is classified into type 1, class 2 group 1 according to 4, ISO 4049:2019.	Filtek Supreme Ultra Flowable Restorative, is a low viscosity, visible-light activated, flowable nanocomposite.	Equivalent

Intended Use(including the indications for use)	- Class III restorations - Class V restorations - Small Class I restorations (non stress-bearing restorations) - Pit and fissure sealing in molars and premolars - Repair of small defects in esthetic indirect inlays - Base/liner under direct restorations	-Class III and V restorations - Restoration of minimally invasive cavity preparations (including small, non stress-bearing occiusal restorations) - Base/liner under direct restorations - Repair of small defects in esthetic indirect restorations - Pit and fissure sealant - Undercut blockout - Repair of resin and acrylic temporary materials	Equivalent
Intended user	Dental professional	Dental professional	Equivalent
Composition of Materials	BISGMA UDMA TEGDMA Ba glass Silane Camphorquinone Ethyl 4-dimethylaminobenzoate Titanium(IV) oxide Yellow ferric oxide Iron(III) oxide Iron(II,III) oxide	BISGMA Substituted Demethacrylate TEGDMA Silane treated ceramic Silane Treated Silica Ytterbium Fluoride (Ybf3) Reacted Polycaprolactone Polymer Diphenyliodonium Hexafluorophosphate	Similar
Applicable standards	ISO 4049 ISO 10993	ISO 4049 ISO 10993	Equivalent
Physical properties			

Compressive strength	277.4(29.4) MPa	317.82 (17.20) MPa	Both met acceptance criteria
Flexural strength	105.24(6.74) MPa	120.96 (18.64) MPa	Both met acceptance criteria
Elastic modulus	8772.3(558.1) MPa	6815.80 (924.00) MPa	Both met acceptance criteria
Depth of cure	A0 - 2.93(0.05) mm UO - 2.66(0.05) mm	2.837(0.13) mm	Both met acceptance criteria
Filler particle size distribution	Silica filler 16nm glass filler 4 ㎛	ytterbium trifluoride filler -0.1 to 5.0 microns Silica filler -non-agglomerated/non-aggregated surface modified : 20 nm, 75 nm zirconia/silica cluster filler - surface modified aggregated(comprised of 20 nm silica and 4 to 11 nm zirconia particles) : 0.6 to 10 microns	Both met acceptance criteria
Surface hardness	26.02(1.83) KHN	45.124(0.16) KHN	Both met acceptance criteria
Radio-opacity	2.7 mmAl	1.70(0.05) mmAl	Both met acceptance criteria

Water sorption	25.24(0.88) µg/mm3	High translucency - 24.87 (2.23) µg/mm3 Medium translucency - 24.48 (1.99) µg/mm3 Low translucency - 28.32 (1.23) µg/mm3	Both met acceptance criteria
Solubility	1.52(0.56) µg/mm3	High translucency - 3.22 (0.20) µg/mm3 Medium translucency - 6.29 (0.23) µg/mm3 Low translucency - 9.77 (0.69) µg/mm3	Both met acceptance criteria
Curing time	20 sec	Curing time : Opaque(Increment depth 1.5mm) - 40 sec All other shade(Increment depth 2.0mm) - 20 sec	Both met acceptance criteria
Intensity for curing	400mW/㎠ (Halogen or LED)	400 mW/cm2 (Halogen or LED)	Equivalent
Wavelength for curing	400-500 nm (Halogen or LED)	400-500 nm (Halogen or LED)	Equivalent
Sterile	Non-sterile	Non-sterile	Equivalent
Shelf Life	3 years	3 years	Equivalent

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

DENU Composite Resin/DENU Flow Resin have the same Indications for Use and the principle of operations as the predicate devices. They are intended to perform as light-cured resin which met the requirement according to ISO 4049. They demonstrate similar physical properties and biocompatibilities with comparable performance specifications to the predicate devices.

The chemical compositions might be slightly different from the predicate devices, however subject devices and predicate devices use same resin matrix based on BISGMA, UDMA and TEGDMA. Other compositions such as filler, photoinitiator, and pigment operate under the same principle of operations.

The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that DENU Composite Resin/DENU Flow Resin is substantially equivalent to the predicate devices. Hence, its equivalent is acceptable.

9. CONCLUSION

HDI Inc. believes that DENU Composite Resin and DENU Flow Resin are substantially equivalent to the legally marketed predicate device. They do not introduce new indications for use, has similar technological characteristics and do not introduce any new safety or effectiveness concerns.