January 5, 2024

Prevest Denpro Limited
℅ Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K231263
Trade/Device Name: Prevest Denpro Composite Resins: Fusion Core DC Flo, Fusion Flo, Fusion Flo SE, Fusion I-Seal, and Magna NT
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: December 7, 2023
Received: December 8, 2023

Dear Angela Blackwell:

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.

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, 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)*
K231263

Device Name
Prevest Denpro Composite Resins Fusion Core DC Flo, Fusion Flo, Fusion Flo SE, Fusion I Seal, and Magma NT

Indications for Use *(Describe)*
Fusion Core DC Flo is indicated for use as core build up material on vital and non-vital teeth, sealing root canal openings, cavity floor liner, post cementation, restorative material, and as a dentin replacement material.

Fusion Flo is indicated for direct filling of class V (cervical caries, root erosions, and wedge shaped defects), anterior restorations(Class III and IV), small posterior restorations, repair of composite/ceramic veneers, and blocking out of undercuts.

Fusion Flo SE is indicated for direct filling of class V (cervical caries, root erosions, wedge shaped defects), anterior restorations (Class III and IV), small posterior restorations.

Fusion I-Seal is indicated for Class I and Class II restorations, as a liner under composite restorations, and as a pit and fissure sealant.

Magma NT is indicated for direct restoration in anterior and posterior teeth classes I, II, III, IV and V, and porcelain/ composite repairs.

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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Prevest DenPro Composites (Fusion Core DC Flo, Fusion Flo, Fusion Flo SE, Fusion I Seal, Magma NT)
510(k) Summary - K231263
January 4, 2024

Name and Address: Prevest Denpro Limited
Unit II, Export Promotion Industrial Park
Bari Brahmana, Jammu 181133 India
Contact Person: Atul Modi
Email: prevestindia@gmail.com
Telephone: (941) 919 4280

Name of device: Prevest Denpro Composites (Fusion Core DC Flo, Fusion Flo, Fusion Flo SE, Fusion I Seal, Magma NT)
Classification Name: tooth shade resin material
CFR: 21 CFR 872.3690
Primary Product Code: EBF
Regulatory Class: II

Submission Contact:
Angela Blackwell
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P.O. Box 718
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Device Description:

Fusion Core DC Flo is dual-curing, radiopaque, flowable restoration for core build-up composite supplied in an auto-mix delivery system.

Fusion Flo is a flowable composite of medium viscosity used for fillings in anterior teeth and small fillings in posterior teeth. Fusion Flo can be used separately or with Magma-NT composites.

Fusion Flo SE is a self-etch, self-adhesive flowable composite. The flowable composite is ready for use and doesn't require the prerequisite preparatory steps of etching, priming and bonding. Fusion Flo SE can be used separately or with Magma-NT composites.

Fusion I-Seal is a single component, light cured flowable composite.

Magma-NT is a visible light cured, radio opaque highly filled hybrid composite restorative material for anterior and posterior restoration of all teeth.

Indications for Use:

Device Name	Indications
Fusion Core DC Flo	Fusion Core DC Flo is indicated for use as 1. Core build up material on vital and non-vital teeth 2. Sealing root canal openings, 3. Cavity floor liner, 4. Post cementation, 5. Restorative material 6. Dentin replacement material.
Fusion Flo	Fusion Flo is indicated for direct filling of • class V restorations (cervical caries, root erosions, wedge shaped defects). • Anterior restorations (Class III & IV). • Small posterior restorations • Repair of composite/ceramic veneers • Blocking out of undercuts
Fusion Flo SE	Fusion Flo SE is indicated for direct filling of • class V (cervical caries, root erosion, wedge shaped defects). • Anterior restorations (Class III & IV) • Small posterior restorations
Fusion I Seal	Fusion I-Seal is indicated for Class I and Class II restorations, as a liner under composite restorations, and as a pit and fissure sealant.
Magma NT	Magma NT is indicated for -direct restoration in anterior and posterior teeth Classes I, II, III, IV and V -porcelain/composite repairs.

Testing Summary:

Fusion Core DC Flo was tested for appearance, flexural strength, film thickness, water sorption, water solubility, working time, and setting time according to protocols based on ISO 4049: 2019 and tested for radio-opacity according to a protocol based on ISO 4049:2019 & ISO 13116:2014.

Fusion Flo, Fusion Flo SE and Magma NT were tested for appearance, flexural strength, sensitivity to ambient light, depth of cure, water sorption, water solubility, and color & shade stability according to protocols based on ISO 4049: 2019 and tested for radio-opacity according to a protocol based on ISO 4049:2019 & ISO 13116:2014. Fusion Flo SE was also tested for pH according to a protocol based on USP 971.

Fusion I Seal was tested for appearance, flexural strength, depth of cure, water sorption and water solubility according to protocols based on ISO 4049:2019, and radio-opacity according to a protocol based on ISO 4049:2019 and ISO 13116: 2014.

All test results met the criteria in standards.

Shelf life for the composites other than Fusion Core DC Flo is 3 years. Fusion Core DC Flo has a shelf life of 2 years. All shelf life determinations use the same testing protocols as the characterization testing which are based on ISO 4049:2019. The predicate and reference devices use the same ISO standard for their testing. Their shelf lives are 3 years or are not given.

Predicate Device: Opallis K201707, Build-it Total Core K102703, Tetric Evoflow K993783, Constic K102603

Reference Devices: everX Posterior K153127, Cal LC K212457, Tetric Evoceram K042819, Opallis Flow K201707, Evadyne K111666

Substantial Equivalence:

The composites have similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing.

Composite Materials from Prevest Denpro

	Fusion Core DC Flo	Build-It Total Core K102703 From Sybron Predicate Device	everX Posterior K153127 from GC America Reference Device	Cal LC K212457 from Prevest Denpro Reference Device
Product Code	EBF	EBF	EJK	EJK
Indications for Use	Fusion Core DC Flo is indicated for use as 1. Core build up material on vital and non-vital teeth 2. Sealing root canal openings, 3. Cavity floor liner, 4. Post cementation, 5. Restorative material 6. Dentin replacement material.	Build-it Total Core is indicated for use as 1. Core build up material on vital and non-vital teeth 2. Sealing root canal openings, 3. Cavity floor liner, 4. Post cementation, 5. Restorative material 6. Dentin replacement material.	everX Posterior is indicated for use as a fiber reinforced composite for the restoration of prepared carious teeth, including large posterior cavities with loss of dentin.	Cal LC is indicated for use as a cavity liner and pulp capping material. It is self-adhering and highly filled.
Mechanism of Action	Dual cure core build-up materials consist of a resin matrix, fillers, and a combination of light curing photopolymerizing agents and chemical curing agents. This	Dual cure core build-up materials consist of a resin matrix, fillers, and a combination of light curing photopolymerizing agents and		

	offers the assurance of complete curing even in areas that may be hard to reach for the curing light. Curing times vary but are often completed within 5 minutes. The dual cured composite at the top surface is mainly polymerized through photo-initiated chemical reactions, while at the bottom surface it is done via chemically initiated polymerization.	chemical curing agents. This offers the assurance of complete curing even in areas that may be hard to reach for the curing light. Curing times vary but are often completed within 5 minutes. The dual cured composite at the top surface is mainly polymerized through photo-initiated chemical reactions, while at the bottom surface it is done via chemically initiated polymerization.		
Applicable Standards	ISO 4049, 13116:2014	ISO 4049	ISO 4049, ISO 9917-2	ISO 4049, ISO 9917-2
Composition	**Base:** • Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Triethylene Glycol Dimethacrylate • Silanated Barium Borosilicate Glass Powder • Silanated Fumed Silica	• Trietylene glycol dimethyl acrylate • Urethane dimethyl acrylate • Fluoride • Barium borosilicate glass fillers • 4-META	• Bisphenol A Glycidyl Methacrylate • polymethylmethacrylate • Triethylene glycolDimethacrylate. • Salinated E-glass fiber • Barium Glass	• Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Silanated Barium Borosilicate Glass Powder • Silanated Amorphous Silica • Calcium Hydroxide • Barium

	• Butylated hydroxy toluene (BHT) • Fumed Silica • Benzoyl peroxide • Yetterbium Fluoride **Catalyst:** • Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Triethylene Glycol Dimethacrylate • Silanated Barium Glass Powder • Silanated Fumed Silica • Camphorquinone • Butylated hydroxy toluene (BHT) • Fumed Silica • Yetterbium Fluoride • Ethyl -4-dimethyl amino benzoate • 2-dimethyl amino ethyl Methyacrylate			sulphate • DL Camphorquinone • 2-Dimethyl Amino Ethyl Methacrylate • Ethyl4Dimethyl Amino Benzoate • Butylated Hydroxy Toluene.

	• Dihydroxy ethyl p-toluidiene • Titanium Dioxide			
Flexural Strength	≥50 MPa	Complies with ISO 4049	Complies with ISO 4049	96.3 MPa
Light Intensity (mW/cm^2) And Curing Time (sec)	≤600 40 750 20 1200 10	≥600 20	>1200 10 700 20	
Wavelength for Curing (nm)	400-450	400-450	400-450	
Depth of Cure (mm)	Not applicable	10mm	4mm	
Working Time (min:sec) Dual Cure	1:25			
Setting Time (min:sec) Dual Cure	3:20			
Filler particle size (µ)	2			0.3-10
Filler loading (% Volume)	65			45.8
Radio Opacity	3mm compared with aluminium wedge	Complies with ISO 4049, 13116:2014	Complies with ISO 4049	Complies with ISO 13116:2014
Water Sorption	maximum of 40 µg/mm3	Complies with ISO 4049	Complies with ISO 4049	Complies with ISO 4049
Water Solubility	maximum of 7.5 $\mu m/mm^3$.	1 g/L	Complies with ISO 4049	Complies with ISO 4049

	Fusion Flo	Opallis Flow K201707 from FGM Dental Group Reference Device	Tetric Evoflow K993783 from Ivoclar Predicate Device
Product Code	EBF	EBF	EBF
Indications for Use	Fusion Flo is indicated for direct filling of	Base/lining underneath direct restorations. - Small, non-occlusal stress-bearing class I restorations	• Class V restorations (cervical caries,

	• class V restorations (cervical caries, root erosions, wedge shaped defects). • Anterior restorations (Class III & IV). • Small posterior restorations • Repair of composite/ceramic veneers • Blocking out of undercuts	according to minimally invasive filling therapy - Pit and fissure sealant. - Tunnel-type preparation. - Repair of enamel defects. - Bonding of tooth fragments. - Repairs in composite resin. - Non-carious cervical lesions . - Planning of preparation walls	root erosion, wedge shaped defects) • Anterior restorations (Class III and IV) • Small posterior restorations • Restorative therapy for mini-cavities of all types (preparation with Sonic-Sys Micro Instruments from Kavo) • Adhesive cementation of Sonic-Sys inlays • Extended fissure sealings in molars and pre-molars • Repair of composite/ceramic veneers • Blocking out of undercuts • Adhesive cementation of ceramic and composite restorations
Mechanism of Action	Flowable resin-based composites are conventional composites with the filler loading reduced by volume as compared to conventional composites. This altered filler loading modifies the viscosity of these materials. The flowable composites are packed in small syringes that allow for easy dispensing with very small gauge needles. This makes them ideal for use in small	Flowable resin-based composites are conventional composites with the filler loading reduced by volume as compared to conventional composites. This altered filler loading modifies the viscosity of these materials. The flowable composites are packed in small syringes that allow for easy dispensing with very small gauge needles. This makes them ideal for use in small	Flowable resin-based composites are conventional composites with the filler loading reduced by volume as compared to conventional composites. This altered filler loading modifies the viscosity of these materials. The flowable composites are packed in small syringes that allow for

	preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	easy dispensing with very small gauge needles. This makes them ideal for use in small preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.
Composition	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Barium Glass Powder • Fumed Silica • Silanated Amorphous Silica • camphorquinone • Ethyl 4-(dimethyl amino benzoate) • 2-Dimethylethylmethacrylate • Butylated Hydroxy Toluene • Titanium Dioxide • Iron oxide	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Fillers: Barium-Aluminum, silanized • Silicate • silicon dioxide • camphoroquinone • accelerators • stabilizers and pigments.	• Ba-Al-silicate glass • Copolymer • Mixed oxide • Ytterbium Trifluoride • Silicone dioxide
Applicable Standards	ISO 4049, 13116:2014	ISO 4049	ISO 4049
Flexural Strength	≥ 80 MPa	137.80 MPa	114 MPa

Light Intensity (mW/cm^2) And Curing Time (sec)	≤600 40 750 20 1200 10	≥500 40	≥500 10
Wavelength for Curing (nm)	400-450	400-500	400-500
Depth of Cure	1.00 mm (opaque) / 1.5 mm (others) minimum	≤2mm	≥1.5mm dentin and bleach XL ≥2mm other shades
Filler particle size (μ)	1	0.05-5	1
Filler loading (% Volume)	62	72	61
Water Sorption	≤40 μg/mm3	27.92 μg/mm³	21.0 μg/mm³
Water Solubility	maximum of 7.5 μm/mm³	5.46 μg/mm³	0.1 μg/mm³
Sensitivity to Ambient Light	Physically homogeneous	Physically homogeneous	≥180s
Radio Opacity	3mm compared with aluminium wedge	2.49 mm	≥1mm Al

	Fusion Flo SE	Tetric Evoflow K993783 from Ivoclar Predicate Device	Constic K102603 from DMG America Reference Device	Cal LC K212457 from Prevest Denpro Reference Device
Product Code	EBF	EBF	EBF	EJK
Indications for Use	Fusion Flo SE is indicated for direct filling of • class V (cervical caries, root erosion, wedge shaped defects). • Anterior restorations (Class III & IV). • Small posterior restorations	• Class V restorations (cervical caries, root erosion, wedge shaped defects) • Anterior restorations (Class III and IV) • Small posterior restorations • Restorative therapy for mini-cavities of all types (preparation with Sonic-Sys	Constic is a light-cured, self-etching, self-adhesive, radiopaque, flowable restorative composite used for many clinical indications such as Class I and Class II restorations, an adhesive liner under composite restorations, as a pit and fissure sealant, or for repairs and modifications to	Cal LC is indicated for use as a cavity liner and pulp capping material It is self adhering and highly filled

		Micro Instruments from Kavo) • Adhesive cementation of Sonic-Sys inlays • Extended fissure sealings in molars and pre-molars • Repair of composite/ceramic veneers • Blocking out of undercuts • Adhesive cementation of ceramic and composite restorations	existing or provisional restorations	
Mechanism of Action	Self-adhesive composites rely on the presence of functional monomers (10-MDP) making them able to surpass the use of an adhesive or an acid etching step. MDP has two groups – a methacrylate group, which copolymerizes with other monomers, and a functional phosphate group, separated by a chain of 10 carbons. Due to its chemical structure and hydrophobicity, it forms a stable calcium salt that is more hydrolytically resistant. The flowable composites with functional monomers	Self-adhesive composites rely on the presence of functional monomers (10-MDP) making them able to surpass the use of an adhesive or an acid etching step. MDP has two groups – a methacrylate group, which copolymerizes with other monomers, and a functional phosphate group, separated by a chain of 10 carbons. Due to its chemical structure and hydrophobicity, it forms a stable calcium salt that is more hydrolytically resistant. The flowable composites with functional monomers offer self-etching and	Self-adhesive composites rely on the presence of functional monomers (10-MDP) making them able to surpass the use of an adhesive or an acid etching step. MDP has two groups – a methacrylate group, which copolymerizes with other monomers, and a functional phosphate group, separated by a chain of 10 carbons. Due to its chemical structure and hydrophobicity, it forms a stable calcium salt that is more hydrolytically resistant. The flowable composites with functional monomers	

	offer self-etching and self-adhesive properties. They are packed in small syringes that allow for easy dispensing with very small gauge needles. This makes them ideal for use in small preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	self-adhesive properties. They are packed in small syringes that allow for easy dispensing with very small gauge needles. This makes them ideal for use in small preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	offer self-etching and self-adhesive properties. They are packed in small syringes that allow for easy dispensing with very small gauge needles. This makes them ideal for use in small preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	
Composition	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Silanated Barium Glass Powder • Silanated Silica • Fumed Silica • camphorquinone	• Ba-Al-silicate glass • Copolymer • Mixed oxide • Ytterbium Trifluoride • Silicone dioxide	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Triethylene Glycol Dimethacrylate • Barium glass in BIS GMA resin matrix from dental resins. • Fillers • Pigments • 10-MDP	• Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Silanated Barium Borosilicate Glass Powder • Silanated Amorphous Silica • Calcium Hydroxide • Barium sulphate • DL

	• Ethyl 4-(dimethyl amino benzoate) • 2-Dimethyl ethyl metha acrylate • Butylated Hydroxy Toluene • 10 –MDP • Titanium Dioxide • Iron Oxide			Camphorquin one • 2-Dimethyl Amino Ethyl Methacrylate • Ethyl4Dimeth yl Amino Benzoate • Butylated Hydroxy Toluene.
Applicable Standards	ISO 4049, 13116:2014	ISO 4049	ISO 4049	ISO 4049, ISO 9917-2
Flexural Strength	≥ 80 MPa	114 MPa	Complies with ISO 4049	96.3 MPa
Light Intensity (mW/cm^2) And Curing Time (sec)	750 40 1200 20	≥500 10	>400 20	
Wavelength for Curing (nm)	400-450	400-500	450	
Depth of Cure	1.00 mm (opaque) / 1.5 mm (others) minimum	≥1.5mm dentin and bleach XL ≥2mm other shades	Complies with ISO 4049	Complies with ISO 4049
Filler particle size (μ)	2	1	0.02-2.3	0.3-10
Filler loading (% Volume)	68	61	43	45.8
Water Sorption	≤40 μg/mm3	21.0 μg/mm^3	Complies with ISO 4049	Complies with ISO 4049
Water Solubility	maximum of 7.5 μm/mm^3	0.1 μg/mm^3	1 g/L	Complies with ISO 4049
Sensitivity to Ambient Light	Physically homogeneous	≥180s	Physically homogeneous	
Radio Opacity	3mm compared with aluminium wedge	≥1mm Al	Complies with ISO 4049	Complies with ISO 13116:2014

	Fusion I Seal	Constic K102603 from DMG America Predicate Device	Evadyne K111666 from Neodent Reference Device	Cal LC K212457 from Prevest Denpro Reference Device
Product Code	EBF	EBF	EBG	EJK
Indications for Use	Fusion I-Seal is indicated for Class I and Class II restorations, as a liner under composite restorations, and as a pit and fissure sealant.	Constic is a light-cured, self-etching, self-adhesive, radiopaque, flowable restorative composite used for many clinical indications such as Class I and Class II restorations, an adhesive liner under composite restorations, as a pit and fissure sealant, or for repairs and modifications to existing or provisional restorations	Evadyne is a light cured single-component material for the temporary restoration of crowns, bridges, or similar dental prostheses. Evadyne is intended for the general dental patient population.	Cal LC is indicated for use as a cavity liner and pulp capping material. It is self-adhering and highly filled
Mechanism of Action	Glass filler fluoroaluminosilicate composites are filled composites which are flowable and have physical and mechanical properties which include the release of fluoride. The flowable composites are packed in small syringes that allow for easy dispensing	Self-adhesive composites rely on the presence of functional monomers (10-MDP) making them able to surpass the use of an adhesive or an acid etching step. MDP has two groups – a methacrylate group, which copolymerizes with other	Glass filler fluoroaluminosilicate composites are filled composites which are flowable and have physical and mechanical properties which include the release of fluoride. The flowable composites are packed in small syringes that allow for easy dispensing	

	with very small gauge needles. This makes them ideal for use in small preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	monomers, and a functional phosphate group, separated by a chain of 10 carbons. Due to its chemical structure and hydrophobicity, it forms a stable calcium salt that is more hydrolytically resistant. The flowable composites with functional monomers offer self-etching and self-adhesive properties. They are packed in small syringes that allow for easy dispensing with very small gauge needles. This makes them ideal for use in small preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to	with very small gauge needles. This makes them ideal for use in small preparations that would be difficult to fill otherwise. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	

		a depth of 2 to 3mm.		
Composition	• Bisphenol A Glycidyl Methacrylate • Urethane Dimethacrylate • Silanated Barium Glass Powder • Barium Sulphate • FluoroAlumino silicate Glass Powder • Silanated fumed Silica • camphorquinone • Ethyl 4-(dimethyl amino benzoate) • 2-Dimethyl ethyl metha acrylate • Butylated Hydroxy Toluene	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Triethylene Glycol Dimethacrylate • Barium glass in BIS GMA resin matrix from dental resins. • Fillers • Pigments • 10-MDP	• Bisphenol A Glycidyl Methacrylate • Urethane Dimethacrylate • FluoroAlumino silicate Glass • Ethyl 4-(dimethyl amino benzoate) • Pigments • Additives • Catalyst • Inorganic filler Particles	• Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Silanated Barium Borosilicate Glass Powder • Silanated Amorphous Silica • Calcium Hydroxide • Barium sulphate • DL Camphorquinone • 2-Dimethyl Amino Ethyl Methacrylate • Ethyl4Dimethyl Amino Benzoate • Butylated Hydroxy Toluene.
Applicable Standards	ISO 4049, 13116:2014	ISO 4049	ISO 4049, ISO 10477	ISO 4049 , ISO 9917-2
Flexural Strength	≥ 25 MPa	Complies with ISO 4049	Complies with ISO 4049	96.3 MPa
Light Intensity (mW/cm^2) And Curing Time (sec)	≤600 40 750 40 1200 10	>400 20		
Wavelength for	400-450	450		

Curing (nm)				
Depth of Cure	1.5 mm minimum	Complies with ISO 4049	Complies with ISO 4049	Complies with ISO 4049
Filler particle size (μ)	5	0.02-2.3		0.3-10
Filler loading (% Volume)	40	43		45.8
Water Sorption	≤40 μg/mm3	Complies with ISO 4049		Complies with ISO 4049
Water Solubility	maximum of 7.5 μm/mm³	1g/L		Complies with ISO 4049
Radio Opacity	3mm compared with aluminium wedge	Complies with ISO 4049		Complies with ISO 13116:2014

	Magma NT	Opallis K201707 from FGM Dental Group Predicate Device	Tetric Evoceram K042819 from Ivoclar Reference Device
Product Code	EBF	EBF	EBF
Indications for Use	Magma NT is indicated for -direct restoration in anterior and posterior teeth Classes I, II, III, IV and V -porcelain/composite repairs.	The composite is suitable for use in permanent and deciduous teeth: -Direct restorations in anterior and posterior teeth Classes I, II, III, IV, V and VI. -Direct veneers with composites. -Cementation of tooth fragments. - Core build-ups. -Teeth splinting. -Diastema closing or reduction. -Modification of teeth´s shape (e.g.: conoid teeth). -Porcelain/composite repairs	• Anterior restorations (Class III and IV) • Class V restorations (cervical caries, root erosion, wedge shaped defects) • Restorations in the posterior region (Class I and II) • Veneering of discolored anterior teeth • Splinting of mobile teeth • Repair of composites and ceramic veneers

Mechanism of Action	Dental composites, also known as resin-based composites, are a blend of polymeric matrix with a dispersion of glass, mineral or resin filler particles and/or short fibers. The filler particles and/or fibers are mixed with the matrix using coupling agents. Dental composites are applied to replace tooth structures that have been damaged or destroyed due to caries or other diseases. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	Dental composites, also known as resin-based composites, are a blend of polymeric matrix with a dispersion of glass, mineral or resin filler particles and/or short fibers. The filler particles and/or fibers are mixed with the matrix using coupling agents. Dental composites are applied to replace tooth structures that have been damaged or destroyed due to caries or other diseases. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.	Dental composites, also known as resin-based composites, are a blend of polymeric matrix with a dispersion of glass, mineral or resin filler particles and/or short fibers. The filler particles and/or fibers are mixed with the matrix using coupling agents. Dental composites are applied to replace tooth structures that have been damaged or destroyed due to caries or other diseases. The photosensitive initiator system and a light source are used to activate the light-cure resin, which is delivered as a single paste and can only cure to a depth of 2 to 3mm.
Composition	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Silanated Barium Glass Powder • Amorphous Fumed Silica	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Fillers: Barium-Aluminum, silanized silicate • silicon dioxide • camphoroquinone	• Ba-Al-silicate glass • Copolymer • Mixed oxide • Ytterbium Trifluoride

	• Camphorquinone • Butylated hydroxy toluene (BHT) • 2-dimethyl amino ethyl Methyacrylate • Ethyl-4 Di methyl amino benzoate • Titanium Dioxide • Iron oxide	• accelerators • stabilizers and pigments	
Applicable Standards	ISO 4049, 13116:2014	ISO 4049	ISO 4049
Flexural Strength	≥ 80 MPa	93.38 MPa	120 MPa
Light Intensity (mW/cm^2) And Curing Time (sec)	≤600 40 750 20 1200 10	≥450 20-60	≥500 10
Wavelength for Curing (nm)	400-450	400-500	400-500
Depth of Cure	2.59 mm (opaque) / 2.89 mm (non-opaque)	≤1.5mm	≥1.5mm dentin ≥2mm other shades
Filler particle size (μ)	2	0.04-3	1
Filler loading (% Volume)	10	57.5	79
Water Sorption	≤40 μg/mm3	28.93 μg/mm^3	21.2 μg/mm^3
Water Solubility	maximum of 7.5 μm/mm^3	5.53 μg/mm^3	<1.0 μg/mm^3
Sensitivity to Ambient Light	Physically homogeneous	Physically homogeneous	≥180s
Radio Opacity	3mm compared with aluminum wedge	2.46 mm	≥1mm Al

Conclusion: Prevest Denpro composites are substantially equivalent to the predicate devices Opalis and Opalis Flow K201707. They have the same indications, the same wavelength for curing, similar curing times, similar testing, and very similar ingredients. Curing times are all within 10-40 secs for both the subject devices and predicate devices so similar enough that the differences would not be noticed when treating a patient. Both the subject devices and the predicate device have physical parameters which meet requirements of the relevant ISO standards. Shelf life testing is similar to the shelf life testing of predicate or reference device. Reference devices are included to cover any ingredients, or indications not covered by the predicate devices. Any differences in ingredients are minor and do not change the substantial equivalence.