May 13, 2021

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

Re: K200555
Trade/Device Name: Prevest Denpro Dental Cements (Micron Bioactive, Micron Superior, Micron Superior Capsules, Micron Luting, Micron Dentin Conditioner)
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: February 2, 2021
Received: February 12, 2021

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 (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,

For Michael Adjodha
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200555

Device Name
Prevest Denpro Dental Cements (Micron Bioactive, Micron Superior, Micron Superior Capsules, Micron Luting and Micron Dentin Conditioner)

Indications for Use *(Describe)*

Micron Bioactive
Class III and V, Restoration of cervical erosions and root surface caries,
Core buildup,
Base/Liner
Class I, limited Class II, temporary fillings
Restoration of primary teeth

Micron Superior Shades A1, A2, A3
Class III, Class V, limited Class I
Restoration of primary teeth,
Core buildup

Micron Superior Capsules Shades A1, A2, A3
Class III, Class V, limited Class I
Restoration of primary teeth,
Core buildup

Micron Luting
Cementation of all types of metal, porcelain fused to metal, and resin crowns, inlays, onlays, and bridges
Cementation of orthodontic bands
Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns
Base/Liner

Micron Dentin Conditioner
Dentin pre-treatment prior to filling with glass ionomer cement

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.

Prevest DenPro Dental Cements (Micron Bioactive, Micron Superior, Micron Superior Capsules, Micron Luting and Micron Dentin Conditoner)
510K Summary
K200555
May 10, 2021

Name and Address: Prevest Denpro Limited
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 Dental Cements (Micron Bioactive, Micron Superior, Micron Superior Capsules, Micron Luting, and Micron Dentin Conditioner)
Classification Name: dental cement
CFR: 21 CFR 872.3275
Primary Product Code: EMA

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
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Device Description:

Micron Bioactive is a radiopaque, hydroxyapatite modified-glass ionomer cement.

Micron Superior is a radiopaque glass ionomer cement. It comes in shades A1, A2 and A3.

Micron Superior Capsules is a radiopaque glass ionomer cement. Capsules come in shades A1, A2 and A3.

Micron Luting is a radiopaque, self-curing translucent, particle glass-ionomer luting material.

Micron Dentin Conditioner is a mild polyacrylic acid solution designed to remove the dentinal smear layer and to condition dentine, thus enhancing the bond between glass ionomer cement and the dentine.

Indications for Use:

Device Name	Indications
Micron Bioactive	Class III and V, Restoration of cervical erosions and root surface caries, Core buildup, Base/Liner Class I, limited Class II, temporary fillings Restoration of primary teeth
Micron Superior	Class III, Class V, limited Class I Restoration of primary teeth, Core buildup
Micron Superior Capsules	Class III, Class V, limited Class I Restoration of primary teeth, Core buildup
Micron Luting	Cementation of all types of metal, porcelain fused to metal, and resin crowns, inlays, onlays, and bridges Cementation of orthodontic bands Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns Base/Liner
Micron Dentin Conditioner	Dentin pre-treatment prior to filling with glass ionomer cement

Testing Summary:

Micron line products were tested for appearance of powder and liquid, opacity, radio-opacity, acid-soluble lead content, setting time, compressive strength, acid erosion, and film thickness according to protocols based on ISO 9917-1 as was appropriate for each material. pH was tested for Micron Dentin Conditioner.

Shelf life testing was completed on all devices using relevant protocols also used for the physical characteristics tested.

All tests results met the criteria in Table 1 of ISO 9917-1.

The dental cements contain ingredients found in the predicate and reference devices so no biocompatibility testing was done.

Primary Predicate Device: ProGlass Cements K101869 from Silmet

Reference Devices: Teethmate K131068 from Kuraray
Ketac Conditioner K872984 from ESPE GMBH
Riva Luting Capsules K040393 from Southern Dental Industries
GlasIonomer FX-2 K031467 from Shofu

Substantial Equivalence:

The acid-base cements have similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing protocols based on ISO 9917-1. Shelf life testing was also similar to the predicate device shelf life testing.

Dental Cements from Prevest Denpro Micron Line

	Subject Device	Predicate Device	Reference Device for additional indications	Reference Device for Hydroxyapatite ingredient	Reference Device for Ingredients
Name	Micron Bioactive	ProGlass Two K101869	ProGlass Silver K101869	Teethmate K131068	GlasIonomer FX-2 K031467
Indications for Use	Class III and V, Restoration of cervical erosions and root surface caries, Core buildup, Base/Liner Class I, limited Class II, temporary fillings Restoration of primary teeth	Class III and V, Restoration of cervical erosions and root surface caries, Core buildup, Base/Liner	Class I, limited Class II, temporary fillings Restoration of primary teeth, Core buildup, Base/Liner	TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments: [I] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion [2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing [3] Treatment of tooth surface before and/ or after bleaching	Glasionomer FX-II is a glass polyalkenoate cement used for dental restorations Glasionomer FX-II is intended for use as a final restorative for deciduous teeth; a geriatric restorative for Class I, 11, Ill and **V** cavities and cervical erosions; a final restorative for Class I and 11 of adult dentition in non-load bearing situations; an intermediate restorative for heavy stress cavities; a core build up; and for pit and fissure fillings.

				[4] Treatment of prepared dentin for fillings and/or prosthetic restorations	
Composition	Powder Fluoroaluminosilicate glass powder and hydroxyapatite powder Liquid Polyacrylic acid solution	Powder Alumino-silicate glass and silver Liquid Polyacrylic acid	Powder Alumino-silicate glass and silver Liquid Polyacrylic acid	Hydroxyapatite	Powder: Fluoroaluminosilicate glass, pigments and fluorescent material Liquid: Acrylic acid tri-carboxylic acid co-polymer solution, tartaric acid Cocoa butter: Cocoa butter, white vaseline
Setting Time	1:30 – 2 min	3:10 min	4 min	N/A	2:30 min

	Subject Device	Predicate Device	Reference Device for Ingredients
Name	Micron Superior	ProGlass Two K101869	GlasIonomer FX-2 K031467
Indications for Use	Class III, Class V, limited Class I Restoration of primary teeth, Core buildup	Class III, Class V, limited Class I Restoration of primary teeth, Core buildup	Glasionomer FX-II is a glass polyalkenoate cement used for dental restorations Glasionomer FX-II is intended for use as a final restorative for deciduous teeth; a geriatric restorative for Class I, 11, Ill and **V** cavities and cervical erosions; a final restorative for Class I and 11 of adult dentition in non-load bearing situations; an intermediate restorative for heavy stress cavities; a core build up;

			and for pit and fissure fillings.
Composition	Powder Fluoroaluminosilicate glass powder Liquid Polyacrylic acid	Powder Alumino-silicate glass and polyacrylic acid Liquid Polyacrylic acid and distilled water	Powder: Fluoroaluminosilicate glass, pigments and fluorescent material Liquid: Acrylic acid tri-carboxylic acid co-polymer solution, tartaric acid Cocoa butter: Cocoa butter, white vaseline
Setting Time	A1 3:30-3:35 min A2 5:20-5:30 min A3 3:15-3:20 min	3:10 min	2:30 min

	Subject Device	Predicate Device	Reference Device for Ingredients
Name	Micron Superior Capsules	ProGlass Two K101869	Riva Luting Capsules K040393
Indications for Use	Class III, Class V, limited Class I Restoration of primary teeth, Core buildup	Class III, Class V, limited Class I Restoration of primary teeth, Core buildup	Suitable for cementation of crowns, bridges, inlays and orthodontic bands. Also suitable for sealing interface between restoration and tooth and base / liner in deep restorations.
Composition	Powder Fluoroaluminosilicate glass powder Liquid Polyacrylic acid	Powder Alumino-silicate glass and polyacrylic acid Liquid Polyacrylic acid and distilled water	Powder Fluoro Aluminosilicate Glass Polyacrylic Acid Liquid Polyacrylic acid Tartaric Acid water
Working Time	1:30 min	1:30-2 min	unknown
Setting Time	A1 3:30-3:35 min A2 5:20-5:30 min A3 3:15-3:20 min	3:10 min	unknown

	Subject Device	Predicate Device	Reference Device for Ingredients
Name	Micron Luting	ProGlass One K101869	GlasIonomer FX-2 K031467
Indications for Use	Cementation of all types of metal, porcelain fused to metal, and resin crowns, inlays, onlays, and bridges Cementation of orthodontic bands Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns Base/Liner	Cementation of all types of metal, porcelain fused to metal, and resin crowns, inlays, onlays, and bridges Cementation of orthodontic bands Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns Base/Liner	Glasionomer FX-II is a glass polyalkenoate cement used for dental restorations Glasionomer FX-II is intended for use as a final restorative for deciduous teeth; a geriatric restorative for Class I, 11, Ill and **V** cavities and cervical erosions; a final restorative for Class I and 11 of adult dentition in non-load bearing situations; an intermediate restorative for heavy stress cavities; a core build up; and for pit and fissure fillings.
Composition	Powder Fluoroaluminosilicate glass powder Liquid Polyacrylic acid with thin viscosity	Powder Alumino-silicate glass and polyacrylic acid Liquid Polyacrylic acid and distilled water	Powder: Fluoroaluminosilicate glass, pigments and fluorescent material Liquid: Acrylic acid tri-carboxylic acid co-polymer solution, tartaric acid Cocoa butter: Cocoa butter, white vaseline
Setting Time	2:30 min	3:10 min	2:30 min

	Subject Device	Predicate Device
Name	Micron Dentin Conditioner	Ketac Conditioner K872984
Indications for Use	Dentin pre-treatment prior to filling with glass ionomer cement	Dentin pre-treatment prior to filling with glass ionomer cement

Composition	Polyacrylic acid solution	Polyacrylic acid solution

Shelf life testing for all 5 devices is 3 years (testing for two devices was done on each of 3 shades) and used the same physical parameters protocols as the testing. This is the same type of protocols as the shelf life testing for the predicate devices from Silmet but the current shelf life of those devices is unknown.

Conclusion: Prevest Denpro Powder/Liquid Acid-Base dental cements are substantially equivalent to the predicate devices, ProGlass. They have the same indications, similar testing (including shelf life testing), and very similar ingredients. Both the subject devices and the predicate devices have setting times which meet requirements of ISO 9917-1 Table 1 for the respective type of cement. 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.