August 18, 2023

Ultradent Product, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K232498
Trade/Device Name: UltraSeal XT plus - Bioprotection by Nobio, UltraSeal XT hydro - Bioprotection by Nobio
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and fissure sealant and conditioner
Regulatory Class: Class II
Product Code: EBC, EBF
Dated: August 14, 2023
Received: August 17, 2023

Dear Dave Yungvirt:

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 -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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)*
K232498

Device Name
UltraSeal XT plus Bioprotection by Nobio
UltraSeal XT hydro Bioprotection by Nobio

Indications for Use *(Describe)*
UltraSeal XT plus bioprotection by Nobio sealant – UltraSeal XT plus sealant for prophylactic sealing of pits and fissures and can be used where the use of a flowable composite is indicated. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.

UltraSeal XT hydro bioprotection by Nobio sealant – Use UltraSeal XT hydro sealant for prophylactic sealing of pits and fissures. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.

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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K232498

510(k) Summary

This summary of the 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 UltraSeal XT plus Bioprotection by Nobio and UltraSeal XT plus Bioprotection by Nobio.

I. Applicant's Name and Address

Ultradent Product, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Contact Person:	Ruth Gardner
Title:	Regulatory Affairs Specialist II
Telephone:	801-553-4431
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Date Summary Prepared: July 31, 2023

II. Name of the Device

Device:	Pit and fissure sealant and conditioner
Trade/Device Name:	UltraSeal XT plus Bioprotection by Nobio UltraSeal XT hydro Bioprotection by Nobio
Common Name:	Sealant, pit and fissure, and conditioner Material, Tooth Shade, Resin
Review Panel:	Dental
Regulation Number:	21 CFR 872.3765
Device Class:	Class II
Classification Product Code:	EBC, EBF

III. Device Description

UltraSeal XT plus bioprotection by Nobio sealant and flowable composite – UltraSeal XT plus sealant is a 58% filled, light-cured, radiopaque, methacrylate-based, thixotropic resin sealant. It is used with PrimaDry drying and priming agent to aid in avoiding moisture contamination—which can cause microleakage and poor retention. It is a Type 1 Class 2 Group 1 polymer-based dental restorative flowable resin which is suitable for occlusal surfaces. It can be used where

the use of a flowable is indicated. It is compatible with adhesives and bonding agents. UltraSeal XT plus sealant has a radiopacity value of 1.44 mm of aluminum. Aluminum has a radiopacity equivalent to that of dentin. Thus, 1 mm of material (having a radiopacity equivalent to 1 mm of aluminum) has a radiopacity equivalent to that of dentin—and 2 mm of aluminum is equivalent to enamel. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.
The dimensions of filler particles are as follows:

Component	**Particle size (µm)**
Aluminum Oxide	≤ 0.05
Glass	1.5 ± 0.25

The percentage by volume of filler particles is 33% (total fillers, 19.2 mL/total volume, 57.90 mL* 100)

UltraSeal XT plus sealant shade	**VITA 3D-MASTER®* Shade Guide**
A2 Opaque	A2

*Not a registered trademark of Ultradent Products, Inc.

UltraSeal XT hydro bioprotection by Nobio sealant – UltraSeal XT hydro sealant is a Class 2, 53% filled, light-cured, radiopaque, methacrylate-based, thixotropic resin sealant. It is partly hydrophobic and hydrophilic before it is cured, hydrophobic once cured, and has a self-adhesive quality. UltraSeal XT hydro sealant chemistry provides the option of a visual verification for marginal retention—with the use of a black light upon placement and at recall visits. The UV light is not included in the UltraSeal XT hydro sealant kit. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.

Some of the silica-based filler particles (max 1.2% wt/wt of the total formulation) contained in all the UltraSeal XT plus Bioprotection by Nobio and UltraSeal XT hydro Bioprotection by Nobio are decorated with quaternary ammonium functional groups that are covalently bound to the filler particles' silica core via a silane linker (herein referred to as "QASi"). Following light induced polymerization, QASi particles (produced by Nobio) remain permanently entrapped within the
sealant and destroy microorganisms by contact. As the cell membrane of microorganisms is negatively charged and the QASi particles have strong positive charges, microorganisms are electrostatically attracted to the positively charged cured material's surface resulting in disruption of their cell membrane and immediate microbial lysis.
Both subject devices have a depth of cure ≥ 1.5mm, are curable at wavelengths of 385-515nm and will remain uncured after light exposure while in their primary container. UltraSeal XT plus Bioprotection by Nobio is also indicated for use as a flowable composite. It has a flexural

strength of ≥ 80 MPa, Water Sortpion ≤ 40 μ g/mm3, Water Solubility ≤ 7.5 μ g/mm3, Radio-Opacity, ≥ 1mm of Al, Surface Hardness ≥ 20 HK and Ambient light sensistivity resulting in the product being physically homogeneous after 60 seconds.

IV. Statement of Intended Use

UltraSeal XT plus bioprotection by Nobio sealant – UltraSeal XT plus sealant for prophylactic sealing of pits and fissures and can be used where the use of a flowable composite is indicated. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.

UltraSeal XT hydro bioprotection by Nobio sealant – Use UltraSeal XT hydro sealant for prophylactic sealing of pits and fissures. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.

V. Predicate Device

Predicate Identified:	UltraSeal XT plus K993846 UltraSeal XT hydro K112517 Infinix Universal Composite, Infinix Flowable Composite, Infinix Bulk Fill Flow Composite K201010

VII. Comparison of Technological Characteristics

Predicate technological comparison:

The technology, delivery, and intended use of UltraSeal XT plus bioprotection by Nobio and UltraSeal XT hydro bioprotection by nobio are substantially equivalent to the identified predicate as outlined in Table 5-1:

Table 5-1

UltraSeal XT plus Bioprotection by Nobio:

Descriptive Information/ characteristic	Device: UltraSeal XT plus bioprotection by Nobio	Predicate: UltraSeal XT plus (K993846)	Identified Characteristic Differences and Rationale for Differences
Product Code	EBC EBF	EBC	Same
Indications for Use	UltraSeal XT plus sealant for prophylactic sealing of pits and fissures and can be used where the use of a flowable composite is indicated. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.	UltraSeal XT plus sealant for prophylactic sealing of pits and fissures and can be used where the use of a flowable composite is indicated.	Similar – Subject device introduces the Nobio QASi particles.
Recognized Standards	ISO 6874 ISO 4049 ISO 13485 ISO 14971 ISO 10993 Series ISO 7405 IEC 62366-1	ISO 6874 ISO 4049 ISO 13485 ISO 14971 ISO 10993 ISO 7405 IEC 62366-1	Similar
Intended User	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Characteristics	• Prophylactic sealing of pits and Fissures • Flowable, light cured material. • Nobio QASi Antimicrobial technology	• Prophylactic sealing of pits and Fissures • Flowable, light cured material.	Similar – Subject device introduces the Nobio QASi particles.
Composition	• Methacrylates • Anti-Bacterial (QASi particles) • Photo-initiators	• Methacrylates • Photo-initiator • Glass fillers	Similar – Subject device introduces the Nobio QASi particles.

	• Source of fluoride • Glass filler • Colorant	• Colorant Source of fluoride	
Delivery System or Deployment Methods	Syringe with tip	Syringe with tip	Same
Physical Properties	• Pit & Fissure Sealant, Flowable Composite	• Pit & Fissure Sealant, Flowable Composite	Same
	• Depth of cure ≥ 1.5mm	• Depth of cure ≥ 1.5 mm	Same
	• Curable at wavelengths of 385-515 nm	• Cures with wavelengths of 385 – 515 nm	Similar
	• Curing Intensity ≥ 800 mW/cm2	• Curing Intensity ≥ 800 mW/cm2	Similar
	• Curing time 10 seconds	• Curing time 10 seconds	Same
	• ISO 4049:2019	• ISO 4049:2019	Similar
	• ISO 4049:2019 - Flexural Strength	• ISO 4049:2019 - Flexural strength	Similar
	• Filler Particle Size: Aluminum Oxide ≤ 0.05µm • Glass 1.5 ± 0.25µm • QASi antibacterial Nano Fillers	• Filler Particle Size: Aluminum Oxide ≤ 0.05µm • Glass 1.5 ± 0.25µm	Similar, filler differences contribute to handling and usability differences in products
	• Water sorption – ISO 4049:2019	• Water sorption - ISO 4049:2019	Similar
	• Water solubility – ISO 4049:2019	• Water solubility – ISO 4049:2019	Similar
	• Radio-Opacity - ISO 4049:2019	• Radio-opacity - ISO 4049:2019	Similar
	• Surface Hardness ≥ 20 HK	• Surface hardness ≥ 20 HK	Similar – Reference device value is unknown

	• Fluoride releasing	• Fluoride releasing	The subject device and predicate device are both fluoride releasing. The reference device does not include fluoride
	• Nobio QASi particles	• N/A	Similar – the subject device includes the Nobio QASi particles
	• Shade: A2 Opaque shade (off-white to light yellow)	• Shades: Opaque White, Clear, A1, A2	Similar
	• Hydrophobic	• Hydrophobic	Similar
Biocompatibility and Safety	Tested per ISO 7405, ISO 10993-1 • Physical/Chemical Information • Cytotoxicity • Sensitization • Irritation • Acute System Toxicity • Subacute Systemic Toxicity • Genotoxicity • Implantation Effects	Tested per ISO 7405, ISO 10993-1 •Cytotoxicity •Sensitization •Mutagenicity	UltraSeal XT plus Bioprotection by Nobio, predicate and reference device is shown to be biocompatible.

UltraSeal XT hydro Bioprotection by Nobio:

Descriptive Information/ characteristic	UltraSeal XT hydro bioprotection by Nobio	Predicate: UltraSeal XT hydro (K112517)	Identified Characteristic Differences and Rationale for Differences
Product Code	EBC	EBC	Same
Indications for Use	Use UltraSeal XT hydro sealant for prophylactic sealing of pits and fissures. The addition of the bioprotection by Nobio reduces demineralization, which is part of the caries formation process.	Use UltraSeal XT hydro sealant for prophylactic sealing of pits and fissures.	Similar – Subject device introduces the Nobio QASi particles.
Recognized Standards	ISO 6874 ISO 13485 ISO 14971 ISO 10993 Series ISO 7405 IEC 62366-1	ISO 6874 ISO 13485 ISO 14971 ISO 10993 ISO 7405 IEC 62366-1	Similar
Intended User	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same.
Characteristics	• Prophylactic sealing of pits and Fissures • Nobio QASi Antimicrobial technology	• Prophylactic sealing of pits and Fissures	Similar – Subject device introduces the Nobio QASi particles.
Composition	• Methacrylates • Anti-Bacterial (QASi particles) • Lowering pH • Photo-initiator • Source of fluoride • Colorant • Glass filler	• Methacrylates • Photo-initiator • Glass fillers • Colorant Source of fluoride	Similar – Subject device introduces the Nobio QASi particles.

Delivery System or Deployment Methods	Syringe with tip	Syringe with tip	Same
Physical Properties	• Pit & Fissure Sealant	• Pit & Fissure Sealant	Same
	• Depth of cure ≥ 1.5mm	• Depth of Cure ≥ 1.5 mm	Same
	• Curable at wavelengths of 385-515 nm	• Curable at wavelengths of 385-515 nm	Similar
	• Curing Time 10 seconds	• Curing Time 10 seconds	Same
	• Nobio QASi particles	• N/A	Similar – the subject device includes the Nobio QASi particles
	• Fluoresces	• Fluoresces	The subject and predicate device have a fluorescing feature. The reference device does not.
	• Curing Intensity ≥ 800 mW/cm2	• Curing Intensity ≥ 800 mW/cm2	Similar
	• Shade: A2 Opaque shade (off-white to light yellow)	• Shades: Opaque White, and Natural Shades	Similar
	• Hydrophilic	• Hydrophilic	Similar
Biocompatibility and Safety	Tested per ISO 7405, ISO 10993-1 • Physical/Chemical Information • Cytotoxicity • Sensitization • Irritation • Acute System Toxicity • Subacute Systemic Toxicity • Genotoxicity • Implantation Effects	Tested per ISO 7405, ISO 10993-1 •Irritation •Cytotoxicity •Sensitization •Mutagenicity	UltraSeal XT plus Bioprotection by Nobio, predicate and reference device is shown to be biocompatible. .

VIII Non-Clinical Performance Testing:

Non-clinical and biological testing was completed to assess the performance and biocompatibility of the UltraSeal XT plus Bioprotection by Nobio and UltraSeal XT hydro Bioprotection by Nobio and to support substantial equivalence. The data provided in this 510(k) submission shows that the sealant is biocompatible based on the biocompatibility assessment conducted as per ISO 10993 and ISO 7405 and performs as intended based on the bench testing per ISO 4049 and ISO 6874. The list of these tests is provided in Table 5-1.

Biocompatibility:
Chemical Characterization
MEM Elution Assay
Guinea Pig Maximization Sensitization
Oral Mucosal Irritation Test
Bench Testing:
UltraSeal XT plus Bioprotection by Nobio
Depth of Cure
Curable at Wavelengths 385-515 nm
Flexural Strength
Ambient Light Sensitivity
Water Sorption
Water Solubility
Radio-opacity
Knoop Hardness
Opaque Delivery System
Medium Viscosity Liquid
Fluoride Release
Hydrophobic Components
Shade and Color
Inclusion of Nobio QASi Particles
UltraSeal XT hydro Bioprotection by Nobio
Depth of Cure
Curable at Wavelengths 385-515 nm
Opaque Delivery System
Fluoride Release
Fluorescing Agent
Shade and Color
Hydrophilic Components
Inclusion of Nobio QASi Particles

Conclusion:

The predicate and subject devices have identical indications for use with a slight variation highlighting the inclusion of the Nobio QASi particles that reduces demineralization. Reference device, Infinix Flowable composite (K201010), intended for use as a flowable composite and/or pit and fissure sealant, incorporates the same Nobio QASi particles that reduces demineralization. Like the predicate devices, the subject devices utilized ISO 6874 and ISO 4049 to evaluate performance aspects of the devices. Safety is further proven by testing conducted to ISO 10993-1 and ISO 7405 supporting the biological safety of the devices. Lastly, device efficacy is met with clinical acceptance as being an effective pit and fissure sealant and as a flowable restorative (UltraSeal XT plus Bioprotection by Nobio only) through simulated use testing with representative users. As such, the differences in indications for use between the predicate and subject devices does not impact safety or effectiveness of the devices.

Based on this, the similar intended use and testing information presented above for the predicate products, UltraSeal XT plus and UltraSeal XT hydro, and the subject products, UltraSeal XT plus Bioprotection by Nobio and UltraSeal XT hydro Bioprotection by Nobio, are substantially equivalent.