July 29, 2021

Largent Health, LLC
% Elizabeth O'Keeffe
Regulatory Affairs Director
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K210115
Trade/Device Name: FiteBac CC OrthoSeal
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket adhesive resin and tooth conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: May 28, 2021
Received: June 1, 2021

Dear Elizabeth O'Keeffe:

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

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 on last page.*

510(k) Number *(if known)*
K210115

Device Name
FiteBac® CC OrthoSeal

Indications for Use *(Describe)*

FiteBac® CC OrthoSeal with K18 QAMS is a light cure primer intended to prepare the tooth surface prior to bonding orthodontic appliances to etched enamel.

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.

510(k) SUMMARY: FiteBac® CC OrthoSeal (K210115)

Company Name: Largent Health, LLC
3698 Largent Way NW, Suite 101
Marietta, GA 30064
Phone: 770-218-6221

Date Prepared: July 28, 2021

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

Applicant Name:
Largent Health, LLC
3698 Largent Way NW, Suite 101
Marietta, GA 30064
Phone: 770-218-6221
Establishment Registration Number: 3015709927

2. **Contact Person:**

Elizabeth O'Keeffe, Ph.D.
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3. **Device Name and Classification:**

Trade Name:	FiteBac® CC OrthoSeal
Classification Name:	Bracket adhesive resin and tooth conditioner
Common Name:	Adhesive, Bracket and Tooth Conditioner
Classification Panel:	Dental
Regulation Number:	21 CFR §872.3750
Device Class:	II
Product Codes:	DYH

4. Primary Predicate Device:

Trade Name:	Ultradent Opal® Seal™
510(k) Clearance:	K090355
Clearance Date:	April 29, 2009
Classification Name:	Bracket adhesive resin and tooth conditioner
Common Name:	Adhesive, Bracket and Tooth Conditioner
Classification Panel:	Dental
Regulation Number:	21 CFR §872.3750
Device Class:	II
Product Codes:	DYH

Predicate Device:

Trade Name:	Transbond Light Cured Orthodontic Adhesive (Transbond XT Primer)
510(k) Clearance:	K880393
Clearance Date:	March 31, 1988
Classification Name:	Bracket adhesive resin and tooth conditioner
Common Name:	Adhesive, Bracket and Tooth Conditioner
Classification Panel:	Dental
Regulation Number:	21 CFR §872.3750
Device Class:	II
Product Codes:	DYH

Reference Device:

Trade Name:	Orthodontic Acrylic 2
510(k) Clearance:	K163482
Clearance Date:	May 31, 2017
Classification Name:	Denture relining, repairing, or rebasing resin.
Classification Panel:	Dental
Regulation Number:	21 CFR §872.3760
Device Class:	II
Product Codes:	EBI

5. Device Description:

The FiteBac® CC OrthoSeal is a 5% K18 Quaternary Ammonium Methacrylate (QAMS) functionalized, light cured orthodontic sealant used to prepare etched enamel for orthodontic bonding.

Technological Characteristics:

The subject device has substantially equivalent technological characteristics as the predicate devices and/or the reference device in terms of principles of operation, intended use, material performance, and biocompatibility.

6. Indications for Use:

FiteBac® CC OrthoSeal with K18 QAMS is a light cure primer intended to prepare the tooth surface prior to bonding orthodontic appliances to etched enamel.

7. Substantial Equivalence:

FiteBac® CC OrthoSeal has the same intended use, principles of operation and substantially equivalent technological characteristics as Ultradent's Opal® Seal™ (K090355). Although FiteBac® CC OrthoSeal differs from the predicate devices in the presence of K18 QAMS, FiteBac® CC OrthoSeal and the reference device Lang Orthodontic Acrylic 2 both contain this same K18 QAMS compound. Both the subject device and the predicate devices have been shown to prime teeth surfaces without negatively effecting the bond strength of orthodontic adhesives. FiteBac® CC OrthoSeal is as safe and effective as the predicate and reference comparator devices currently cleared for marketing in the United States. Additional biocompatibility and non-clinical testing demonstrate FiteBac® CC OrthoSeal is as safe and effective as these devices and does not raise additional questions of safety and effectiveness.

8. Comparison of Technological Characteristics with the Predicate devices:

A comparison of the subject device to the predicate devices and reference device is shown in the following table.

Characteristics	Subject Device FiteBac® CC OrthoSeal	Primary Predicate Ultradent Opal® Seal™ K090355	Predicate Device Transbond Light Cured Orthodontic Adhesive (Transbond XT Primer) K0880393	*Reference Device Lang Orthodontic Acrylic 2 K163482	Comparison Results
Indication for Use Statement	FiteBac® CC OrthoSeal with K18 QAMS is a light cure primer intended to prepare the tooth surface prior to bonding orthodontic appliances to etched enamel.	Opal® Seal is a light cure primer that is used when bonding orthodontic appliances to etched enamel.	N/A	N/A	Comparable
Principle of Operation	Methacrylate Sealant	Methacrylate Sealant	Methacrylate Sealant	Methacrylate-based material	Equivalent to predicates
Available Configurations	Liquid	Liquid in a single barrel syringe	Liquid	Liquid and Powder	Equivalent to predicate devices
Size	6 mL	1.2- or 3-mL Syringe	6 mL	Multiple Sizes	Equivalent to secondary predicate device
Package	Polyethylene Bottles	NA	Polyethylene Bottles	Polyethylene Bottles	Equivalent to secondary predicate device

Characteristics	Subject Device FiteBac® CC OrthoSeal	Primary Predicate Ultradent Opal® Seal™ K090355	Predicate Device Transbond Light Cured Orthodontic Adhesive (Transbond XT Primer) K0880393	*Reference Device Lang Orthodontic Acrylic 2 K163482	Comparison Results
Biocompatibility	Yes - see table 12.2.1	Yes	Yes	Yes	Equivalent to predicate devices

CC OrthoSeal Light Curing Specification Comparison with Ultradent Opal® Seal™ (K090355)				
Characteristics	**Subject Device FiteBac® CC OrthoSeal K210115**		**Primary Predicate Ultradent Opal® Seal™ K090355**	
Time to Cure	10 seconds	20 seconds	20 seconds	10 seconds
Wavelength	< 600 mW/cm^2	≥ 600 mW/cm^2	< 600 mW/cm^2	≥ 600 mW/cm^2

***Reference Device Comparison Rationale:** The reference device Lang Orthodontic Acrylic 2 (K163482) was chosen as a technological reference due to both the subject device and the reference device containing K18 QAMS. See relevant data provided in MAF2174.

9. Non-clinical Testing – Bench Study Comparison

The subject device has mechanical properties substantially equivalent to commercially available devices with the same intended uses. The following characteristics were evaluated:

Performance Testing:

- Bond Strength Testing

Non-clinical Testing – Biocompatibility:

- Sensitization
- Cytotoxicity
- Irritation

Testing Summary:

Results of all conducted testing was found acceptable and do not raise any new issues of safety or effectiveness.

10. Performance Standards:

FiteBac® CC OrthoSeal complies with the following performance standards:

Recognition #	Area	Title of Standard	Reference Number and Date	Standards Development Organization
2-258	Biocompatibility	Biological Evaluation of Medical Devices – Part 1: Evaluation in Testing Within a Risk Management Process	10993-1:2018	ISO
2-245	Biocompatibility	Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity	10993-5:2009	ISO
2-174	Biocompatibility	Biological Evaluation of Medical Devices – Part 10: Tests for Skin Irritation and Delayed Hypersensitivity	0993-10:2010	ISO

11. Conclusion as to Substantial Equivalence:

The FiteBac® CC OrthoSeal is comparable to listed Predicate Devices and any differences do not raise new questions of safety and effectiveness. When compared to marketed devices, performance data demonstrates that the FiteBac® CC OrthoSeal is at least as safe and effective as the Predicate Devices listed in this submission.