January 23, 2020

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

Re: K190271
Trade/Device Name: FiteBac Cavity Cleanser
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: LBH
Dated: January 8, 2020
Received: January 14, 2020

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,

For Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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 on last page.*

510(k) Number *(if known)*
K190271

Device Name

FiteBac® Cavity Cleanser

Indications for Use *(Describe)*

The FiteBac® Cavity Cleanser is a 2% K21 QAS aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations.

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.

K190271

6 510(k) Summary

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the FiteBac® Cavity Cleanser is provided below.

Date	February 8, 2019
Submitted by	Largent Health, LLC 3698 Largent Way NW, Suite 101 Marietta, GA 30064 Phone: 770-218-6221
510(k) Contact	Secure BioMed Evaluations Elizabeth O'Keeffe, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) Regulatory@SecureBME.com
Trade Name	FiteBac® Cavity Cleanser
Common Name	Varnish, Cavity
Code –Classification	LBH: Class II
Predicate Device	K915668 Bisco Cavity Cleanser
Reference Device	K070070 Ascent Dental Cleanser
Reference Device	K163482 Lang Orthodontic Acrylic 2

Device Description

The FiteBac® Cavity Cleanser is a 2% K21 Quaternary Ammonium Silane-functionalized (QAS) aqueous ethanolic solution intended for cleansing and moistening/re-wetting of prepared dental surfaces. It is recommended for use upon completion of tooth preparation or etching, prior to sealing dentinal tubules. Research has shown that FiteBac® Cavity Cleanser can not only remove debris in carious lesion preparations but can penetrate exposed dentin tubules allowing restorative adhesives to tightly bind to the prepared dentin surface. Clinical studies have not been conducted to demonstrate that this device results in improved clinical outcomes.

Intended Use

The FiteBac® Cavity Cleanser is a 2% K21 QAS aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations.

Technological Characteristics

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

Non-clinical Testing – Bench Study Comparison

The subject device has mechanical and physical 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

- Cytotoxicity
- Sensitization

Substantial Equivalence Summary (Conclusion)

FiteBac® Cavity Cleanser has the same intended use, principles of operation and substantially equivalent technological characteristics as the predicate device Bisco Cavity Cleanser (K915668) and the reference device Ascent Dental Cleanser (K070070). Although FiteBac® Cavity Cleanser differs from the predicate and reference devices in the source of solution component (K21 QAS versus Chlorhexidine Digluconate), FiteBac® Cavity Cleanser and the reference device Lang Orthodontic Acrylic 2 both use the same functionalized quaternary ammonium molecule found in the FiteBac® QAS molecule as a source of product component. The subject device and the predicate and reference devices active ingredients have been shown to effectively cleanse and prepare carious lesions for restoration without diminishing restoration bond strength. FiteBac® Cavity Cleanser 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® Cavity Cleanser is as safe and effective as these devices and does not raise additional questions of safety and effectiveness.

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

Trait	FiteBac® Cavity Cleanser™	Bisco Cavity Cleanser (Predicate)	Ascent Dental Cleanser (Reference)	Lang Orthodontic Acrylic (Reference)	Comparison/ Equivalent to
510(k) number	TBD	K915668	K070070	K163482	N/A
FDA Regulation	872.3260	872.3690	872.3260	872.3760	Equivalent to reference
Product Code	LBH	EBF	LBH	EBI	Equivalent to reference

Trait	FiteBac® Cavity Cleanser™	Bisco Cavity Cleanser (Predicate)	Ascent Dental Cleanser (Reference)	Lang Orthodontic Acrylic (Reference)	Comparison/ Equivalent to
Product Classification	Class II	Class II	Class II	Class II	Equivalent to predicate and reference devices
Use	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Equivalent to predicate and reference devices
Intended Use	The FiteBac® Cavity Cleanser is a 2% K21 QAS aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations	BISCO's Cavity Cleanser is a 2% chlorhexidine digluconate aqueous solution intended for cleansing and moistening/re-wetting cavity preparations.	The Ascent Dental Cleanser is indicated for the cleansing and disinfecting only of tooth cavity preparations in conjunction with dental restorative procedures	Orthodontic Acrylic 2 is intended for the fabrication of methacrylate-based orthodontic appliances (such as retainers, bite guards, and bite plates, etc.)	Equivalent to predicate
Principle of Operation	Cleansing and re-wetting of carious preparations	Cleansing and re-wetting of carious preparations	Cleansing of carious preparations	Fabricating orthodontic appliances	Equivalent to predicate
Composition	2% K21 QAS	2% Chlorhexidine Digluconate	Chlorhexidine Gluconate	5% K18 QAMS	Equivalent to reference device
Available Configurations	Liquid	Liquid	Liquid	Liquid, Powder	Equivalent to predicate and reference devices
Size	8 mL	7 mL or 150 mL	unknown	Multiple sizes	N/A
Package	Low Density Polyethylene Bottles	7 mL: Low Density Polyethylene 135 mL: High Density Polyethylene	unknown	High Density Polyethylene Bottles	Equivalent to predicate
Biocompatibility	Yes	Yes	unknown	Yes	Equivalent to predicate and reference devices