June 25, 2020

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

Re: K200614
Trade/Device Name: FiteBac Antimicrobial Cavity Cleanser
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: March 28, 2020
Received: May 28, 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)*

K200614

Device Name

FiteBac® Antimicrobial Cavity Cleanser

Indications for Use *(Describe)*

The FiteBac® Antimicrobial Cavity Cleanser with 2% K21 QAS is an antimicrobial 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.

K200614

6 510(k) Summary

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

Date	March 6, 2020
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® Antimicrobial Cavity Cleanser
Common Name	Varnish, Cavity
Code –Classification	LBH: Class II
Predicate Device	K190271 FiteBac® Cavity Cleanser

Device Description

The FiteBac® Antimicrobial Cavity Cleanser is an antimicrobial 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. FiteBac® Antimicrobial Cavity Cleanser acts on the microorganisms in the table below, and not only removes debris in carious lesion preparations but can penetrate exposed dentin tubules allowing restorative adhesives to tightly bind to the prepared dentin surface. *In vitro* studies, referenced below, demonstrated a reduction in the following microorganisms.

Microorganisms Susceptible to FiteBac® Antimicrobial Cavity Cleanser
Streptococcus mutans[1]
Actinomyces naeslundii[1]
Lactobacillus acidophilus[2]
Candida albicans[3]

[1] Gou YP, Li JY, Meghil MM, et al. Quaternary ammonium silane-based antibacterial and anti-proteolytic cavity cleanser. Dent Mater. 2018;34(12):1814-1827.
[2] Daood U, Burrow MF, Yiu CKY. Effect of a novel quaternary ammonium silane cavity disinfectant on cariogenic biofilm formation. Clin Oral Investig. 2020;24(2):649-661.
[3] Data on File

Indications for Use

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

Technological Characteristics

As the subject device is identical in formulation and manufacture, the subject device has substantially equivalent technological characteristics to the predicate device in terms of principles of operation, intended use, material performance, and biocompatibility.

Non-clinical Testing – Bench Study Comparison

As the subject device has the same formulation and manufacturing as the predicate device, the subject device has mechanical and physical properties identical to the predicate device. No additional biocompatibility testing was conducted for this submission.

In the referenced literature, the subject device underwent antimicrobial effectiveness testing against *Streptococcus mutans, Actinomyces naeslundii, Lactobacillus acidophilus,* and *Candida albicans*. Briefly, dentin blocks impregnated with each microorganism were treated with the subject device to determine the effectiveness of the subject device at reducing the microorganism from the dentin, resulting in the reduction of each microorganism.

Substantial Equivalence Summary (Conclusion)

FiteBac® Antimicrobial Cavity Cleanser subject device has equivalent intended use, principles of operation and the exact same technological characteristics as the predicate device FiteBac® Cavity Cleanser (K190271). Although the subject device includes and expanded antimicrobial claim, the subject device and the predicate device are the same formulation with the same manufacturing process. FiteBac® Antimicrobial Cavity Cleanser subject device is as safe and effective as the predicate device currently cleared for marketing in the United States and does not raise additional questions of safety and effectiveness.

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

Trait	FiteBac® Antimicrobial Cavity Cleanser™ (Subject Device)	FiteBac® Cavity Cleanser™ (Predicate Device)	Comparison/ Equivalent to
510(k) number	TBD	K190271	N/A
FDA Regulation	872.3260	872.3260	Equivalent
Product Code	LBH	LBH	Equivalent
Product Classification	Class II	Class II	Equivalent
Use	Prescription Use Part 21 CFR 801 Subpart D	Prescription Use Part 21 CFR 801 Subpart D	Equivalent

Trait	FiteBac® Antimicrobial Cavity Cleanser™ (Subject Device)	FiteBac® Cavity Cleanser™ (Predicate Device)	Comparison/ Equivalent to
Indications for Use	The FiteBac® Antimicrobial Cavity Cleanser with 2% K21 QAS is an antimicrobial aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations	The FiteBac® Cavity Cleanser is a 2% K21 QAS aqueous ethanolic solution intended for cleansing and moistening/re-wetting of cavity preparations	Equivalent plus Antimicrobial Claim
Principle of Operation	Cleansing and re-wetting of carious preparations	Cleansing and re-wetting of carious preparations	Equivalent
Composition	2% K21 QAS	2% K21 QAS	Equivalent
Available Configurations	Liquid	Liquid	Equivalent
Size	8 mL	8 mL	Equivalent
Package	Low Density Polyethylene Bottles	Low Density Polyethylene Bottles	Equivalent
Biocompatibility	Yes	Yes	Equivalent