

K200614

## 6 510(k) Summary

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

<b>Date</b>	March 6, 2020
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<b>Trade Name</b>	FiteBac® Antimicrobial Cavity Cleanser
<b>Common Name</b>	Varnish, Cavity
<b>Code –Classification</b>	LBH: Class II
<b>Predicate Device</b>	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
<i>Streptococcus mutans</i> <sup>1</sup>
<i>Actinomyces naeslundii</i> <sup>1</sup>
<i>Lactobacillus acidophilus</i> <sup>2</sup>
<i>Candida albicans</i> <sup>3</sup>

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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
<b>Indications for Use</b>	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
<b>Principle of Operation</b>	Cleansing and re-wetting of carious preparations	Cleansing and re-wetting of carious preparations	Equivalent
<b>Composition</b>	2% K21 QAS	2% K21 QAS	Equivalent
<b>Available Configurations</b>	Liquid	Liquid	Equivalent
<b>Size</b>	8 mL	8 mL	Equivalent
<b>Package</b>	Low Density Polyethylene Bottles	Low Density Polyethylene Bottles	Equivalent
<b>Biocompatibility</b>	Yes	Yes	Equivalent