FiteBac®

September 24, 2021

To whom it may concern,

K18 QAMS is a quaternary ammonium silane molecule functionalized with acrylates. Comprised of a silane core with three acrylate groups and a Si-Quat biocide structure bound to the core, the K18 QAMS has been shown in literature to be effective in reducing biofilm formation via prevention of adhesion to the tooth surface ($p \leq 0.01$) in a simulated oral environment[1].

The K18 QAMS molecule has been previously cleared as a component of a dental sealant (FiteBac CC OrthoSeal in K210115) and as a biofilm reducing component of dental resins (Lang Orthodontic Acrylic 2 in K163482).

The FDA cleared devices containing K18 QAMS are categorized as a breached surface medical device with long term contact duration and as a surface medical device with long term contact duration, thus both the devices underwent cytotoxicity, sensitization, and irritation studies per ISO 10993-1. The following is a list of passing biocompatibility results for FDA cleared K18 QAMS containing medical devices.

Biocompatibility Tests	Result
ISO Cytotoxicity MEM Elution According to ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity	PASS
Oral Mucosal Irritation Study in Hamsters – Collar Method – 14 Day According to ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	PASS
Intracutaneous Injection Test According to ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization and ISO 10993-12, Biological evaluation of medical devices – Part 12: Sample Preparation and Reference Materials	PASS
ISO Guinea Pig Maximization Sensitization Test According to ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	PASS

These previous FDA submissions concluded that the specified cleared K18 containing devices are biocompatible for their intended uses and poses no health risk to the end user[2].

[1] Sticker B, *et al*. Assessment of tethered UDMA-K18 antimicrobial efficacy on biofilm activity. *J Dent Res* 2016;95:Spec Iss A:1019

[2] This previously conducted biocompatibility testing does not constitute passing biocompatibility results for other medical devices, and KGH Chemical does not guarantee that incorporation of K18 QAMS into other medical devices will be biocompatible. FDA requires that every final finished device is tested according to its contact type and duration for the intended use of that device as defined by ISO 10993-1. KHG Chemical does not guarantee the performance and/or biocompatibility of medical devices that incorporate the K18 QAMS molecule.