

K210115 FiteBac CC OrthoSealJul 29, 2021
191 days to decisionK210115 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k210115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Jan 19, 2021
Decision date	Jul 29, 2021
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Largent Health, LLC
Location	Marietta, GA, US
Contact	Kirk Kimmerling
510(k) history	3 submissions · 3 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Elizabeth O'Keefe

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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