

K183147 BrackFixMar 1, 2019
108 days to decisionK183147 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k183147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Nov 13, 2018
Decision date	Mar 1, 2019
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Voco GmbH
Location	Denver, CO, US
Contact	M. Th. Plaumann
Website	https://www.voco.dental
510(k) history	119 submissions · 119 cleared · 1991-2026

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