FDA 510(k) Premarket Notification

K231817 AlignerFlow LC

CLEARED

Dec 1, 2023
163 days to decision

K231817 · Product code: **DYH** · Dental
Source: https://www.510kdatabase.net/k231817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Jun 21, 2023
Decision date	Dec 1, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Voco GmbH**
Location	Denver, CO, US
Contact	Verena Kollek
510(k) history	119 submissions · 119 cleared · 1991-2026