FDA 510(k) Premarket Notification

K250739 Primeprint Direct Aligner

CLEARED

Nov 7, 2025
241 days to decision

K250739 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k250739/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Mar 11, 2025
Decision date	Nov 7, 2025
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dreve Dentamid GmbH**
Location	Unna, DE
Contact	Anke Hüttenbrauck
510(k) history	6 submissions · 6 cleared · 2017-2025