

K241579 DD Hybridlayer (multicolored zirconia)Sep 6, 2024
95 days to decisionK241579 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k241579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jun 3, 2024
Decision date	Sep 6, 2024
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dental Direkt GmbH
Location	Spenge, DE
Contact	Patrick Berz
510(k) history	9 submissions · 9 cleared · 2015-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241579/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026