

K253191 DCMhotbond zirconMay 21, 2026
237 days to decisionK253191 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k253191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Sep 26, 2025
Decision date	May 21, 2026
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dental Creativ Management GmbH
Location	Mecklenburg-Vorpommerin, DE
Contact	Milija Mitrovic
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Trisler Consulting (Db)
Contact	Patsy Trisler

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

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