

**K251084 zirkon**Jun 5, 2025  
57 days to decisionK251084 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k251084/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Powder, Porcelain (EIH)
Date received	Apr 9, 2025
Decision date	Jun 5, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	structure; LFU shades, stains and glazes

**APPLICANT**

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Company	<b>Estetic Ceram AG</b>
Location	Triesen, LI
Contact	Micheal Reise
Website	<a href="https://www.esteticceram.com/">https://www.esteticceram.com/</a>
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Novineon Cro</b>
Contact	Anna Pocsai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251084/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026