

**K241131 edelweiss CAD/CAM T-BLOCK**Oct 18, 2024  
177 days to decisionK241131 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k241131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 24, 2024
Decision date	Oct 18, 2024
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	edelweiss CAD/CAM C-BLOCK; edelweiss CAD/CAM i-BLOCK; Ceramir CAD/CAM T-BLOCK; Ceramir CAD/CAM C-BLOCK; Ceramir CAD/CAM i-BLOCK

**APPLICANT**

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Company	<b>Edelweiss Dentistry Products GmbH</b>
Location	Wolfurt, AT
Contact	Jakob Unterweger
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medagent GmbH</b>
Contact	Leonie Zeller

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/k241131/> 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