

**K010475 D/C CORE MATERIAL**May 7, 2001  
76 days to decisionK010475 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k010475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Feb 20, 2001
Decision date	May 7, 2001
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Parkell, Inc.</b>
Location	Mchenry, IL, US
Contact	NELSON J GENDUSA
510(k) history	53 submissions · 53 cleared · 1976-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010475/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026