

**K053516 MUCOHARD**Jan 26, 2006  
41 days to decisionK053516 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k053516/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Dec 16, 2005
Decision date	Jan 26, 2006
Days to decision	41 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/k053516/> 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