

**K260569 DB 4000 High Impact Denture Base**Jun 2, 2026  
103 days to decisionK260569 · Product code: **EBI** · Dental  
Source: <https://www.510kdatabase.net/k260569/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Feb 19, 2026
Decision date	Jun 2, 2026
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carbon, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Gina Policastro
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Nilo Medical Consulting Group, LLC</b>
Contact	Michael Nilo

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

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260569/> 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 June 9, 2026