

**K230115 Denture Base Resin**Mar 17, 2023  
59 days to decisionK230115 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k230115/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Jan 17, 2023
Decision date	Mar 17, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aidite (Qinhuangdao) Technology Co., Ltd.</b>
Location	Qinhuangdao, CN
Contact	Chen Yingying
510(k) history	16 submissions · 16 cleared · 2020-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Icas Group</b>
Contact	Julie Chen

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/k230115/> 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 14, 2026