

K250534 Biomic Color OpaqueMay 20, 2025
85 days to decisionK250534 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k250534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Feb 24, 2025
Decision date	May 20, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aidite (Qinhuangdao) Technology Co., Ltd.
Location	Qinhuangdao, CN
Contact	Zhanfu Ye
510(k) history	16 submissions · 16 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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.netDevice record: <https://www.510kdatabase.net/k250534/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026