

K243356 Asiga DentaBASEApr 11, 2025
164 days to decisionK243356 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k243356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Oct 29, 2024
Decision date	Apr 11, 2025
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asiga Pty, Ltd.
Location	Alexandria, AU
Contact	Justin Elsey
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Pharmalex Pty, Ltd.
Contact	Keely So

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/k243356/> 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