

**K243370 DentaTOOTH**May 5, 2025  
187 days to decisionK243370 · Product code: **EBG** · Dental  
Source: <https://www.510kdatabase.net/k243370/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Oct 30, 2024
Decision date	May 5, 2025
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Pharmalex Pty, Ltd.</b>
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)

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