

**K010882 BLUE SKY BIO DENTAL IMPLANT SYSTEM**Sep 28, 2001  
189 days to decisionK010882 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k010882/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 23, 2001
Decision date	Sep 28, 2001
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Blue Sky Bio</b>
Location	Irvine, CA, US
Contact	ALBERT ZICKMANN
510(k) history	5 submissions · 5 cleared · 2000-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010882/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026