

**K052968 MODIFICATION TO: ORLUS MINI SCREW**Sep 8, 2006  
322 days to decisionK052968 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k052968/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Oct 21, 2005
Decision date	Sep 8, 2006
Days to decision	322 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortholution Co., Ltd.</b>
Location	Marietta, GA, US
Contact	CATHRYN CAMBRIA
510(k) history	3 submissions · 3 cleared · 2005-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052968/> 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 24, 2026