

K050568 ORLUS MINI SCREWJun 1, 2005
89 days to decisionK050568 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k050568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 4, 2005
Decision date	Jun 1, 2005
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050568/> 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 June 24, 2026