

**K111216 OSSEOTITE 2 DENTAL IMPLANTS**Nov 18, 2011  
200 days to decisionK111216 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k111216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 2, 2011
Decision date	Nov 18, 2011
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet 3i, Inc.</b>
Location	Palm Beach Gardens, FL, US
Contact	MARTHA I GARAY
510(k) history	13 submissions · 13 cleared · 2007-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111216/> 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 16, 2026