

**K113113 ENDOSSEOUS DENTAL IMPLANT**Nov 16, 2012  
393 days to decisionK113113 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k113113/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Oct 20, 2011
Decision date	Nov 16, 2012
Days to decision	393 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ot Medical GmbH</b>
Location	Bremen, DE
Contact	SABINE SCHMAHL
510(k) history	3 submissions · 3 cleared · 2012-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113113/> 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 3, 2026