

**K130999 OSSEOSPEED PROFILE EV**Oct 25, 2013  
198 days to decisionK130999 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k130999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 10, 2013
Decision date	Oct 25, 2013
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentsply Implants Manufacturing GmbH</b>
Location	San Diego, CA, US
Contact	LINDA K SCHULZ
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130999/> 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 8, 2026