

**K133733 WINSIX Implant System**Jan 28, 2015  
418 days to decisionK133733 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k133733/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 6, 2013
Decision date	Jan 28, 2015
Days to decision	418 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosaf IN S.R.L.</b>
Location	Imola, IT
Contact	MAURIZIO PANTALEONI
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133733/> 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 5, 2026