

**K251046 S.I.N. Dental Implant System**Aug 13, 2025  
132 days to decisionK251046 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k251046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 3, 2025
Decision date	Aug 13, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>S.I.N. Implant System Ltda</b>
Location	S?o Paulo, BR
Contact	Denise Domiciano
510(k) history	4 submissions · 4 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251046/> 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 May 14, 2026