

K251129 S.I.N. Tapered Pro Conical Zygoma Implant SystemNov 7, 2025
210 days to decisionK251129 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k251129/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 11, 2025
Decision date	Nov 7, 2025
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Michael Davis Quality and Regulatory Consulting, LLC
Contact	Michael Davis

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251129/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026