

K222231 S.I.N. Dental Implant SystemOct 27, 2022
94 days to decisionK222231 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k222231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 25, 2022
Decision date	Oct 27, 2022
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	S.I.N. ? Sistema DE Implante Nacional S.A.
Location	Sao Paulo, BR
Contact	Denise Domiciano
510(k) history	17 submissions · 17 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin A. Thomas

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/k222231/> 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 26, 2026