

K221453 S.I.N. Dental Implant SystemDec 15, 2022
210 days to decisionK221453 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k221453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 19, 2022
Decision date	Dec 15, 2022
Days to decision	210 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)

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