

K211921 S.I.N. Dental Implant SystemOct 20, 2021
121 days to decisionK211921 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k211921/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Jun 21, 2021 |
| Decision date | Oct 20, 2021 |
| Days to decision | 121 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/k211921/> 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 25, 2026