

K212538 DESS Dental ImplantsDec 14, 2021
124 days to decisionK212538 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k212538/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Aug 12, 2021 |
| Decision date | Dec 14, 2021 |
| Days to decision | 124 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Terrats Medical SL |
| Location | Montcada I Reixac, ES |
| Contact | Roger Terrats |
| 510(k) history | 22 submissions · 22 cleared · 2017-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------------|
| Consulting firm | PaxMed International, LLC |
| Contact | Floyd G. Larson |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212538/> 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