

**K250639 DESS Dental Smart Solutions**May 22, 2025  
80 days to decisionK250639 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k250639/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Mar 3, 2025
Decision date	May 22, 2025
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Enerxen Consulting, Inc.</b>
Contact	Melissa Burbage

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250639/> 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